" A STUDY COMPARING THE EFFICACY AND OUTCOMES OF SUBMUSCULAR PLATING AS COMPARED TO ELASTIC NAILING IN FEMORAL DIAPHYSEAL FRACTURES IN CHILDREN AGED 5-16 YEARS "

A Dissertation submitted to the Tamil Nadu Dr. M.G.R. Medical University in partial fulfillment of the requirement for the award of M.S. Branch II (Orthopaedic Surgery) degree April 2013- 2015

CERTIFICATE

This is to certify that this dissertation titled " A STUDY COMPARING THE EFFICACY AND OUTCOMES OF SUBMUSCULAR PLATING AS COMPARED TO ELASTIC NAILING IN FEMORAL DIAPHYSEAL FRACTURES IN CHILDREN AGED 5-16 YEARS "

Is a bonafide work done by Dr. **DENNIS MARTIN DAVID**, in the department of Paediatric Orthopaedic Surgery, Christian Medical College and Hospital, Vellore in partial fulfilment of the rules and regulations of the Tamil Nadu Dr. M.G.R. Medical University for the award of M.S. Degree (Branch-II) Orthopaedic Surgery, under the supervision and guidance of Professor **THOMAS PALOCAREN**, during the period of his post graduate study from June 2013 – May 2015

This consolidated report presented herein is based on Bonafide cases studied by the candidate.

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ABSTRACT

Title of abstract: A comparative study assessing the efficacy and outcomes of sub-muscular plating and elastic stable intramedullary nailing (ESIN) in paediatric diaphyseal femoral fractures.

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The study was conducted among the age group of 5 to 16 years and 7 patients each were randomised into ESIN or sub-muscular plating groups with mean ages of 9 and 8.71 years. The outcomes assessed were malunion in any plane and functional assessment using PODCI (paediatric outcomes data instrument) scale which was assessed at the end of 6 months. Other serious adverse effects along with duration of surgery, blood loss, radiation exposure and time to union were also assessed. We did not find any malunion or serious adverse effects in either group. The functional scores using PODCI and total radiation exposure were marginally better for the plating group as compared to ESIN but statistically not significant. The duration of surgery, amount of blood loss, hospital stay duration, time to return to school and time to union were better in the ESIN group but were statistically not significant. The comparison observational study for the same age group, found more implant related complications in the nailing group (30%) but more malunion rates in the plating group (10%). Remaining outcomes studied were similar to the prospective arm. The trends of this interim analysis show that sub-muscular plating is a viable option for paediatric diaphyseal fractures but a larger study is needed to come to any definitive conclusions.

Keywords: femur, shaft, submuscular plating, Nailing, malunion, paediatric

CONTENTS

AIM

To compare the efficacy and the outcomes of two operative interventions used for diaphyseal paediatric femur fracture fixation namely elastic stable intramedullary nailing and submuscular locked plating.

OBJECTIVES

The detailed objectives of the study are:

To compare prospectively between two interventions (elastic stable intramedullary nailing and submuscular locked plating) using the following outcomes:

i. Malunion - As per assessment at the end of 6, 12 and 24 months

ii. Serious adverse effects namely

a) Non-union
b) Infection deep surgical wound infection
c) Reoperation
d) Nerve injuries
e) Compartment syndrome
f) Decrease Range of Movement (ROM) in proximal and distal joint as compared to the contralateral side
g) Implant related complications
h) Other complications

iii Functional outcome measures at the end of 6 months, 12 months and 24 months using

a) Paediatric outcomes data collection instrument (PODCI) iv To conduct an observational study with the following criteria

a) To compare the between two interventions (elastic stable intramedullary nailing and sub muscular locked plating) using the above said available outcomes
b) To enrol patients of the same age group as the randomised control group.
c) To enrol patients who have a minimum follow up till the time of radiological and clinical union.
d) The use the observational data as a comparison to the randomised control group.

INTRODUCTION

Fracture of the paediatric femoral shaft amounts to about three percent of all the fractures in the paediatric age group.(1)

It is 2.6 times more common in the males as compared to the females of the same age group in general. There appears to be a bimodal peak in the age distribution of the fracture. (2) With the first peak seen in the early childhood and the second peak in the middle period of adolescence.(3)

About 50 % of deaths of children between 1-15 years are due to trauma and trauma is only 2nd in production of morbidity in children. (4)

The management of femur fractures has evolved over time mainly in the paediatric age group. Various non-operative methods and the introduction of Thomas splint in the late 1800’s and early 1900’s followed by casting and spica application techniques were popular till 1990’s and it was only in the last two decades that various methods of fracture fixation in children have evolved.(5)

With the introduction of concepts of osteosynthesis by the AO group, various modalities have emerged to fix femoral fractures in children. The various methods that are available include external fixation, a dynamic compression plate fixation, Titanium elastic stable intramedullary nailing, rigid intramedullary nailing and submuscular plating. These methods have decreased the time of immobilisation and are less cumbersome for the patient and the caregiver enabling early ambulation and return to function.

The choice of treatment (operative or non operative) and the implant to be used depends on various factors namely, surgeon preference and the experience of surgeon, patient's acceptance, fracture characteristics and family preferences. (6) The associated injuries also influence the treatment modality.(7)

The current well accepted, safe and effective method of paediatric femoral fractures in the age group 5-11 years is Titanium Elastic nailing (TEN). It has revolutionised care and outcome of these injuries with its ease of application, uncomplicated post operative care, safe and stable internal fixation, easy to learn and low rate of complications with early return to physical activities. The small and aesthetic skin incision, low chances of infection and limited hospitalisation period make it a popular option in many settings. (8)

Poor clinical outcomes have been reported with the elastic stable intramedullary nails with

1) Comminuted fractures or segmental fractures.

2) They are ineffective in maintaining the length and alignment of the fractures towards the ends of long bones especially the distal third and proximal third fractures of the femoral shaft

3) poor outcomes also have been reported when the weight of the child is (> than 50 kg).(9)

The Plating techniques using Dynamic Compression Plates required large incisions and fell out of favour when smaller incisions and minimally invasive surgery gained ground.(10)

With the advent of Locked Compression plates in the late 20th century and its subsequent successful use for adult femur fracture, its application for paediatric femur fractures also commenced.

Recently, submuscular plating with small incisions and percutaneous insertion of plates, less blood loss and easier rehabilitation has found favour and has been reported to have better outcomes for proximal third, distal third fractures of the femur and in comminuted fractures. The use of locked compression plate also allowed micromotion at the fracture site without causing any significant reduction in the blood supply to the fracture fragments, thus allowing rapid healing of the fractured bone ends. (11)

However, it is not clear if they have better outcomes for diaphyseal femur fractures when compared with elastic nailing in children. This study was prospectively conducted with randomisation to compare the outcomes and of locked compression plating versus titanium elastic nailing for diaphyseal femoral shaft fractures among paediatric patients in the age group 5-16 yrs.

REVIEW OF LITERATURE

HISTORICAL

Bone setting is not a new art. In fact it was being practiced by our most primitive ancestors. With the active high risk hunting life of the pre-historic man, they must have encountered more often than not the problem of broken bones and developed some methods to deal with this problem or risk losing their lives. Prof. Karl Sudhoff, the famous German historian, wrote that the Neolithic man is the earliest era from which evidence has been recovered showing bones with traces of correction of deformities. The Egyptian papyrus scrolls which were traded by Edwin Smith have a wealth of knowledge and carve a niche in the historical account as they reveal that the Egyptians had a clear and a very scientific understanding of the human anatomy and the effects of trauma on the bones. It has clear illustrated references to the fractures of the long bones (12)

Hippocrates in his writings dating from 320 B.C. spent a large amount of space for the description and treatments of fractures. He was the one who recognised the problems that are ever present with the fracture of the femoral shaft and the possible deformities that are inherent even after the best of treatment has been given. The practice of splinting was present even at that time and he described the splinting methods for the fractures of the shaft of femur. These words of his hold true even after all the centuries have passed, "Extension must be maintained in a straight line with the leg and thigh, whether on accounts of fracture of the bone or of the thigh; And in both cases they are to be bandaged while in extension”. (10)

Sushruta, the father of Indian surgery, in 8^{th} century B.C. described in great detail the types of fractures (Bhagna) and management of the same. He described 8 types of fracture which closely resemble the anatomical fracture classification of the modern times and also described the modality of treatment for the same. He gave due consideration to the factor of age in deciding the prognosis of the fracture. In the principles of treatment he described three steps –

Reduction: anchana (traction), Pedana (manipulation), Samkshepa (opposition).

Retention: Bandhana (immobilisation)

Rehabilitation: Vyayama (exercises)

Considering that the content of these writings are comparable to the modern fracture treatment techniques, highlights the mastery of ancient Indian physician over many medical mysteries. (13)

Abu-Al-Qasim-Al-Zawahiri, also known as Albucasis in the Western world is considered by most to be the greatest physician of the medieval Islamic world. He is also considered to be the father of modern surgery. He developed many instruments and techniques which he recorded in his thirty volume medical encyclopaedia known as Kitab al Tasrif. He is given credit for the introduction of coaptation splints for the femur fracture to prevent the fracture fragments from moving away after reduction. One of his greatest followers, the French surgeon Guy de Chauliac, wrote a book on fracture in detail in which he described the methods of reduction and maintenance in reduced position. He used traction to give isotonic pull for the treatment of femur fracture, which was sustained by suspending a weight over the pulley at the foot of the bed which was tied to the leg with a cord. He practiced in the 14^{th} century but his method of traction is still being followed through the ages. (12)

Sir Percival Pott was the first to realise that the cause of deformities was due to muscle forces around the bone which contract and cause fracture fragments to over-ride. He advocated that the fractured limbs should be kept in the position of ease for the muscles of that limb which meant that the hip and the knee were to be kept in a position of flexion for the femoral shaft fractures. (14)

Hugh Owen Thomas, a famous surgeon of his time, put the knowledge of his bone setting family techniques to work and developed the splint known as the Thomas splint. This invention revolutionised the treatment of the fractures of the long bones and it was particularly known for dealing with the fractures of the lower limb specifically the femur shaft, distal femur and proximal tibia. Initially developed for the purpose of splinting joints afflicted with tuberculosis, the popularity for usage in femur fractures is largely due to the efforts of Hugh Owen Thomas's nephew, Sir Robert Jones. Hugh Owen also developed the modification called the Tobruk splint and achieved excellent immobilisation while still allowing for their transport in a smoother and easier way. All these years, the Thomas splint has seen numerous modifications but it is still used in immobilisation and transport of femur fractures and sometimes as a definitive management for children with femur fractures.(15)

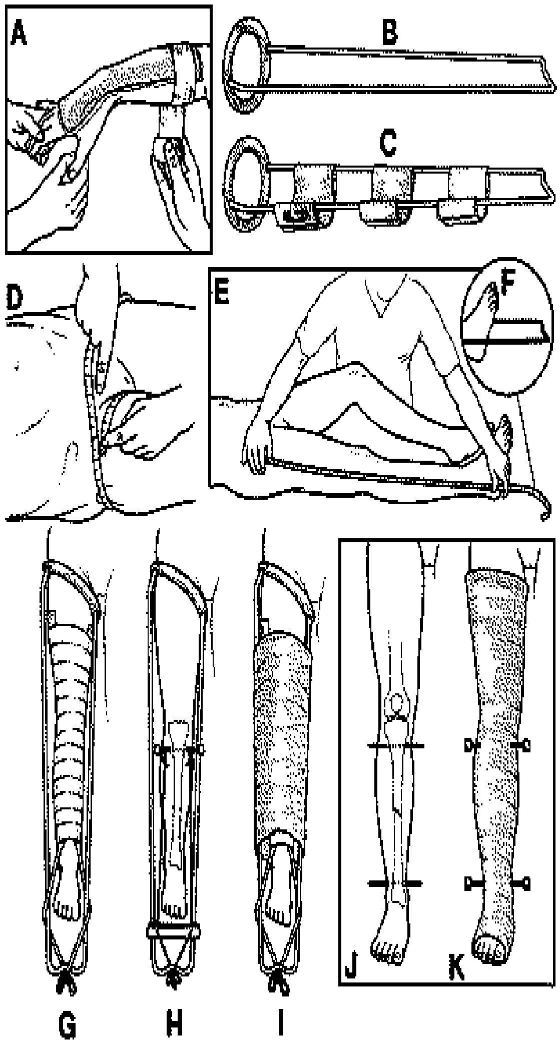


Figure 1- Thomas splint

Figure 2- Modified Tobruk splint

TRACTION

Skin traction was introduced using adhesive plaster to the skin by Josaiah Crosby but was popularised during the civil war by Gordon Buck and thus came to be known as Buck's traction.

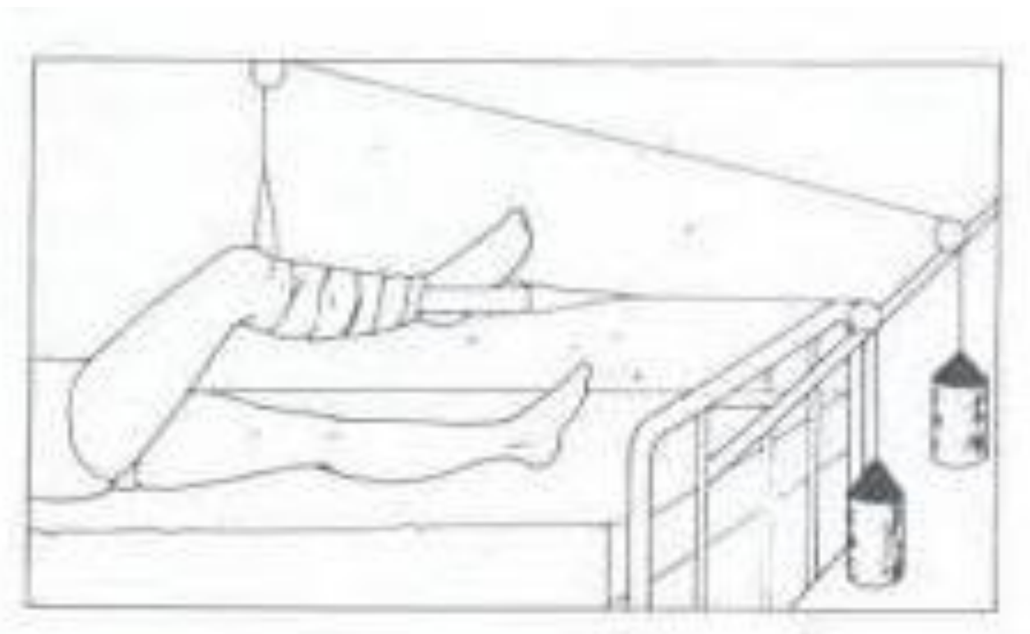
The problem of getting the abducted proximal fragment in line with the distal fragment while maintaining the traction was addressed in a dramatic but effective way by splinting the fractured and the unaffected limb by hoisting them upwards through a bar above the bed. It was first said to be used in the John Hopkins hospital at Baltimore and this method continues to prove its usefulness in some paediatric femur fractures.

Hamilton Russell used traction at 2 points on the limb such that the final vector of traction was in the desired direction even when the knee was flexed. This became more acceptable and ensured patient compliance and became the method of choice for the treatment of femur shaft fractures from 1921 onwards.

Even with all the advances, it became evident that skin traction was not the answer for the problem of the femoral shaft fractures in children and people started looking for other modalities. In a study conducted during Russell's time, only 62% of fractures thus treated were considered to have good outcomes.

Figure 3 - Gallows traction

Figure 4 – The 90 -90 traction



Traction device that grasped the bone itself was first used by Malgaigne in 1847, who designed the hooks that could prevent the displacement of patella fractures by hooking onto the patella.

Fritz Steinmann drove 2 pins into either femoral condyles and used them for traction in the femoral shaft fractures. He further perfected his technique by then driving the pin through and through the femoral condyles and then using it for traction. The usage of this method was further enhanced by the introduction of the Bohler's stirrup.

In 1909, 2 years after Steinmann, Kirschner devised the skeletal traction method using smaller diameter wires. All these techniques were widely used in World War 1 but fell out of favour due to the infection associated with their use. The advancement in the antibiotic world and development of antiseptic techniques for the pins saw the re-emergence of these traction techniques which continue to be used till date.(14)

CASTING

Antonius Mathijsen introduced the world to Plaster of Paris in 1852 and this revolutionised the treatment of fractures. Prior to this, starched bandages were used which required 3 days to set. Plaster of Paris required only 8 minutes to set and thus it became a far superior and acceptable mode of splinting. (14)

Augusto Sarmiento in 1970's popularised functional bracing which entailed a snugly fit cast over the affected limb segment leaving the joints free. There were several advantages to this including faster healing of fractures with lower chances of non-union and malunion, prevention of stiffness of the joints along with no muscular atrophy. This further decreased the immobilisation time and enabled faster return to activity while giving freedom of activity during the bracing period. This while being advantageous also was unable to control the angular deformities during fracture healing. The usual deformities included varus and anterior angulation especially in the proximal half of femur due to the highly deforming muscular forces. Thus , cast bracing became unpopular for these fractures.(16)

Figure 5 - Functional cast bracing

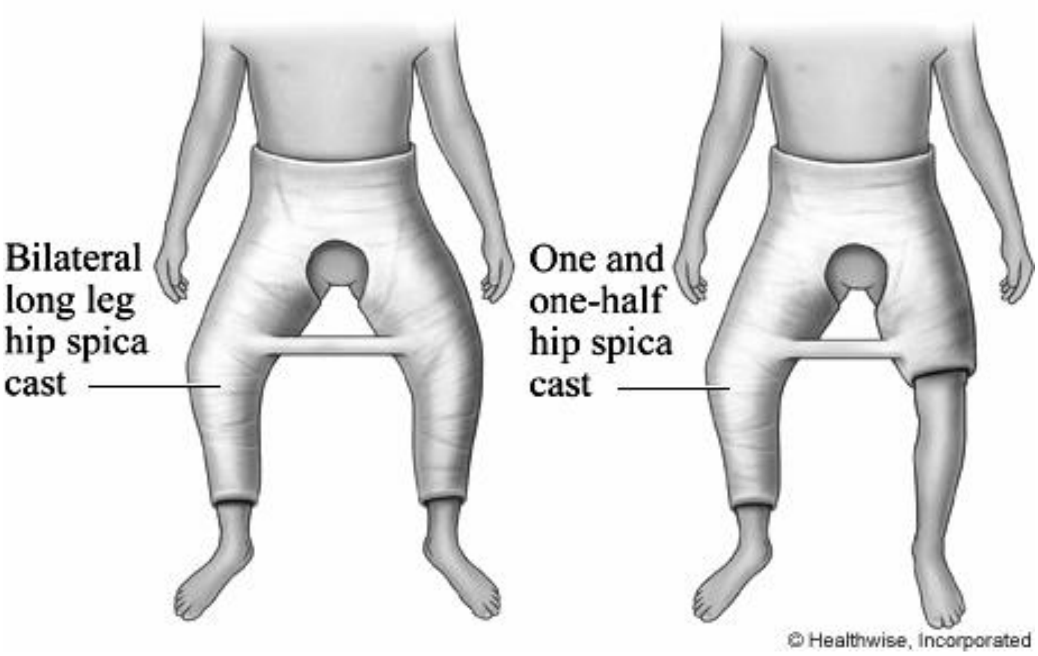


Figure 6 - Hip spica casting

Irani introduced the world to early spica casting in children of all age groups. The cast needed to be well padded at all bony prominences and extended up to the ankle. The advantages of spica casting were that it was easier to apply, it was cost effective and mostly gave good results.(17)

Henderson et al prospectively studied 26 children treated with early spica casting and matched them with 50 patients that were treated with traditional methods and found that the results were as good if not better with spica treatment and, additionally, it saved a lot of inpatient time and cost especially in the less than 10 year age group.(18)

Sugi and Cole in 1987 developed a protocol for the acceptability of reduction in spica casting said to be anterior angulation less than 20° and valgus angulation less than 15° with acceptable limb length discrepancy of less than 10% of the femoral shaft length and obtained good results with the same. (19)

The concept of high and low energy trauma and its effect on femoral shaft fractures were studied by Pollack and associates on 47 fractures treated with spica. They found that 52% of high energy fractures displaced as compared to 8% in the low energy group and recommended close monitoring for the same or use of alternate methods for fixation.(20)

Curtis et al prospectively randomised 91 patients to 2 groups namely the traditional traction followed by spica group and another which were treated with pontoon spica with a 90-90 position of the lower limb. Their results revealed significant reduction in cost, less inconvenience, early healing and thus reduced loss of work and cost and preventing shortening with the second group. (21)

Wright and associates prospectively compared spica casting and external fixation in the ages of 4-10 and found that the spica cast yielded unacceptably high rates of malunion and limb length discrepancy as compared to external fixation. They advised further study of other modalities for fracture treatment in this age group (22)

EXTERNAL FIXATION

One of the earliest advocates of external fixation of the paediatric femoral shaft fractures was Wagner who developed a monolateral frame of external fixation which could double up as a lengthening device. One of the early retrospective case series was from Aronson and Turskey and later with Blasier who gave their experience over 139 fractures over a period of 10 years and concluded that external fixator was a good alternative.(23)

Evanoff prospectively used external fixation for 25 fractures in the head injury or multiply traumatised patients and found excellent results with regards to union and maintenance of reduction.(24)

Hedin et al followed a series of 98 consecutively done uncomplicated and displaced femoral shaft fracture for ages 3-15 found external fixation to be an alternative which could be regularly used to treat such fractures. (25)

These results were not always reproducible and few authors found high rates of pin tract infections, bony overgrowth and re-fracture through pin tracts and therefore, the interest in this modality waned and it became limited to use in open fractures as a temporising tool and for damage control. (26–28)

INTRAMEDULLARY FIXATION

Peltier in one of his review publications attributed Nieham in 1904 with the first report of successful treatment of long bone fractures in children by insertion of an intramedullary device.

Rush L.V and H.L., in their path breaking longitudinal pin splinting technique i.e. Rush pin fixation presented in 1937, dabbled with use in paediatric femoral fractures after successfully using their technique for other long bones. They followed up 47 children in whom open intramedullary Rush pinning was done and found good results for most of the children with minimal complications namely lengthening and mild valgus angulation.(29)

Gerhard Kuntscher demonstrated in 1940 for the first time that osteosynthesis could be achieved along the medullary cavity of the long bones by using a metal object to keep the fracture fragments in place. The technique which was initially described for mid shaft transverse or oblique fractures was then later developed further by Klemm and Schlemann for segmental and comminuted fractures with the addition of interlocks. (30)

These initial successes were followed by reports of osteonecrosis of the femoral head. (31) These were attributed to the injury to the posterior superior branch of the medial circumflex femoral artery, during the pyriformis fossa insertion of the nail. (32)

Firica and his other Romanian colleagues developed the Elastic Stable intramedullary nails using the Ender Instrument set. This revolutionised the intramedullary nailing method especially for the paediatric age group. This method was adopted, further developed and popularised by Metaizeau and colleagues, who popularised the use of dual flexible rods with distal metaphyseal insertion technique and indirect reduction. They published their excellent results in 123 children with minimal complications and thus the ESIN became a popular method of fixation for these fractures. (33)

PLATE FIXATION

Compression to bring bone fragments together and then hold them opposed with very little motion between fragments was first used by Key in 1932 for arthrodesis of the knee joint and Kick first started the use of these devices for internal fixation using compression. Roger Anderson has been credited as the first person to apply the principle of compression plating to fractures.

Muller, Danis and Bagby separately developed compression devices which could be temporarily applied to the ends of the plates to achieve compression.

The dynamic compression plate was then developed which allowed up to 2 mm of compression across the fracture site by virtue of placement of a lag screw across an oblique hole. This obviated the need to further extend skin incisions to apply compression. (34)

In a retrospective study of 51 children with 56 fractures, Ziv and Rang found good results with intramedullary nailing but 3 out of their 5 plating subjects developed deep infections and they concluded that intramedullary nailing was superior to plating methods. (35)

However, many favourable reports for plating in femoral shaft fractures followed in literature. Ward, Hansen and Kregor in separate studies, used plating for femur shaft fractures mainly in the head injured or multiply injured patient for easier nursing and rehabilitation. They found that these patients had a good outcome with satisfactory hip and knee range of movements albeit, with increase in length of 2-20 mm in the affected limbs. They proposed that plating was a good alternative for these fractures. (36–38)

Fyodorov extended the indications of compression plating to isolated femoral shaft fractures. (39) Caird and associates identified 60 children with plate fixation and followed them up to plate removal. There was a 100% union rate with minimal complications which compared favourably with other methods of fixation of these fractures. Till date, this is the largest series of plating for paediatric femoral fractures. (40)

With the advent of locked compression plates and refinement of plating techniques in general by the AO/ASIF group such as using long plates, spanning the plate with lesser number of screws, use of unicortical screws at the end of the plates to minimise the stress riser effect, locked plating method has come to the forefront. The minimally invasive plate osteosynthesis (MIPO) technique has made it possible to use locked plates for femoral shaft fractures as a primary method of fixation. (41)

In 2004, Kanlic reported a series of 51 patients using bridge plating in the sub muscular plane. This allowed retention of the fracture hematoma and use in comminuted fractures without excessive periosteal stripping. The functional outcome was excellent with limb length discrepancy being the only adverse outcome in 8 % of the fractures.(42)

REVIEW OF ANATOMY

EMBRYOLOGY AND DEVELOPMENT

The development of normal limbs begins at the latter part of the 4th week post fertilisation. The mesoderm which is well differentiated now sprouts buds along the sides of the embryo. The development of the limbs occurs in a proximal to distal order from the girdle to the digits. The proximal bones of the limb girdle including the humerus and femur develop before the differentiation of the ridge ectoderm. The rest of the limb bones depend upon the development of the apical ectoderm.(43)

The appearance of femur as said happens by condensation of the mesenchymal stem cells at the end of the 4th week of gestation. It grows by enchondral ossification rapidly and is well defined by the end of 8th week. There is one primary ossification centre at the femoral shaft which continues to ossify and grow in size. In the sixth month of gestation, the proximal secondary ossification centre becomes active which later gives rise to the femoral head and trochanter. The distal secondary ossification centre which forms the femoral condyles becomes active in the seventh month of gestation.

Due to its rapid appearance and its regular growth, femur length is one of the best biometric parameters in fetal ultrasonography and can be used to diagnose conditions like achondrogenesis, achondroplasia and osteogenesis imperfecta types 2 and 3.

The ossification of the femur head occurs at 4-5 months post delivery while that of the greater trochanter happens at approximately 4 years of age. The lesser trochanter is the last to ossify and appears in the radiographs at about 10 years of the child’s life.

Due to the large primary ossification centre of the femur shaft, enchondral ossification takes place there with calcification at the periphery and the vascularity at the centre of the shaft leading to formation of a medullary cavity in these bones. The enchondral ossification lays down woven bone for the shaft which remains as such up to 18 months of child's age. Following this, the bone remodels into a more lamellar adult type.

The bone continues to grow longitudinally and in diameter. The major contribution of the growth comes from the distal femoral physis which appears last accounting for about 70% of the bone length. The proximal physis provides 30% of the total femoral growth.

The growth physis appears as a radiolucent zone on the radiographs till it is active and disappears once the physis fuses, marking the end of skeletal growth. The greater and the lesser trochanter physis fuses at around 17 years of age while the femoral head physis closes at 17-18 years in males and 16-17 years in females. The distal femoral physis fuses last at about 18-19 years in males and 17 in females. (44)

SURGICAL ANATOMY

The femur is the largest long bone in the body. The various parts of femur are the head and the neck, the trochanters, the shaft and the distal end of the bone consisting of the medial and the lateral femoral condyles. Fractures of each part of femur present a unique dilemma and require different techniques of fixation. The muscles acting on the proximal part of the femur are the abductors of which gluteus maximus is the major one and also the Iliopsoas which are the main hip flexors. To the distal parts are attached the gastrocnemius muscle proximal to the posterior condyles and the adductors inserted at the adductor tubercles. These muscle insertions ensure that the fractured fragment get displaced in particular direction. The proximal fragment goes in an extended and abducted position along with external rotation. The distal fragment goes into flexion and internal rotation. The quadriceps tends to cause overriding of the fractured fragments. The distal metaphysis of the femur, 1 inch proximal to the physis, is considered to be a good entry point for the flexible femur nailing. If the fracture is in the proximal half of the femur an alternative proximal entry just distal to or through the lateral border of the trochanter should be considered. Similarly, the diameter of the femoral shaft is used to determine the size of flexible nail. The diameter in antero-posterior and lateral at the isthmus is halved and then 0.5 cm is subtracted. 2 such nails with a similar diameter are used for fixation. Similarly the diameter of external fixator pins should be 1/3rd the diameter of the femoral shaft at the point of insertion.

The standard approach for femoral plating is posterolateral. The femur is approached along the anterior surface of the intermuscular septum with the vastus lateralis being reflected anteriorly. More recently, the femur shaft is approached with small incision after indirect reduction and passage of plate which is done in the subvastus plane. More recently, a medial approach has been advocated with good results.(45)

Since bones are the structural members of the body, they are subjected to a combination of forces in various directions including compression, torsion and bending loads imposed by gravitational, muscular and ligamentous forces. The calculation of strength and rigidity of femur is made by calculating the data from experimental section of femur, from the geometry and the elasticity and rigidity of the bone. If 2 cylinder containing the same amount of metal but varying diameter are compared the hollow greater diameter cylinder is much stiffer and thus the part of femur as a large hollow cylinder to bear weight is well suited for the various forces that act on it while load bearing. (46)

BLOOD SUPPLY

The femur is richly supplied by blood. The endosteal supply is via the nutrient artery which is usually a branch of the 2nd perforator. This artery perforates the linea aspera and arborises proximally and distally to supply the bone. There is usually 1 nutrient artery but sometimes there are two. The outer third of the cortex is supplied by the periosteal vessels. Subsequent to a fracture in the shaft, the blood supply pattern completely changes and the periosteal blood supply takes over as the major blood source to the femur. The endosteal supply gets restored after months. (44)

The blood supply to the head of femur is precarious. The vessels of the ligamentum teres supply blood to the head of femur in early life and the amount of blood supplied gradually decreases and becomes less than 20% by the age of eight years. The medial and the lateral circumflex arteries traverse the neck of femur and then supply the head of femur. The metaphyseal branches gradually decrease in size especially when they cross the physeal cartilage which forms a barrier to the penetration of these arteries. The metaphyseal vessels supply the head of femur till the age of 4 years after which this blood supply is nonexistent.

Once the metaphyseal vessels diminish, the lateral epiphyseal vessel takes over their role. These vessels can penetrate the physeal cartilage and thus these are the vessels that are the predominant source of blood supply to the head of femur. (44)

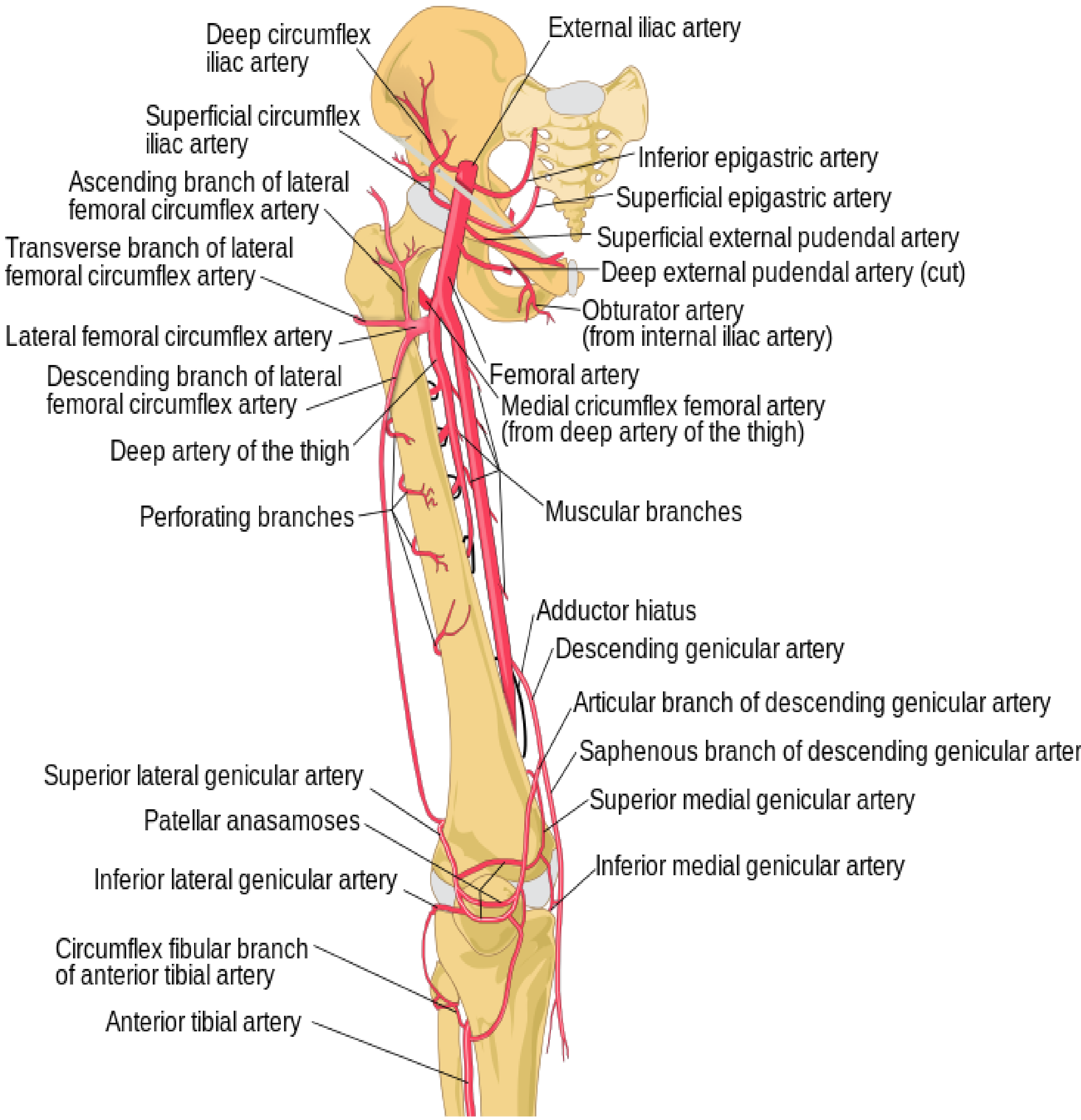


Figure 2 Blood supply of Femur Source – Netter's atlas of anatomy.

It was Ogden who noted the two branches of the lateral epiphyseal vessels namely the posterosuperior and posteroinferior branch which were branches from the medial circumflex artery. At the level of the intertrochanteric groove, these arteries branch into a retinacular arterial system which penetrate the capsule and traverse in the direction of the femoral head. These are the arteries that form the major supply of the femoral head eventually supplying peripherally and proximal to the physis. (47)

At 3-4 years of age, the lateral posterosuperior vessel predominates the supply of the lateral portion of the capital femoral epiphyses. The multiple small vessels coalesce to form a limited number of large vessels as the age increases. As a consequence, damage to a single vessel can cause serious damage to the femoral head and physis.

FRACTURES OF THE FEMORAL SHAFT

Fracture of the paediatric femoral shaft amounts to about three percent of all the fractures in the paediatric age group.(1)

It is 2.6 times more common in the males as compared to the females of the same age group in general. And there appears to be a bimodal peak in the age distribution of the fractures. (2)

The first peak is seen in the early childhood while the second peak appears in the middle period of adolescence.

The major cause of femoral shaft fractures in Indian children is road traffic accidents especially in the urban centres, while in the rural areas; fall from height is another major cause.

In the western countries, the presence of femoral shaft fractures along with other fractures or recurrent injuries raises the suspicion of child abuse.(3)

The femoral shaft fractures can be classified in many ways:

Based on the integrity of the soft tissue envelope – open vs. closed fractures

Location of fracture – proximal, middle or distal third fractures,

Configuration of fractures – transverse, oblique or spiral

Depending on comminution – fracture classification as described by Winquist and Hansen which decides the category of fracture by the amount of contact between the two major fragments post reduction.

Type 0 – 100% contact

Type 1 – more than 75 % contact post reduction

Type 2 - more than 50 % but less than 75% contact post reduction

Type 3 - more than 25 % but less than 50 % contact post reduction

Type 4 – less than 25 % contact post reduction

Figure 7 - Winquist and Hansen type 0

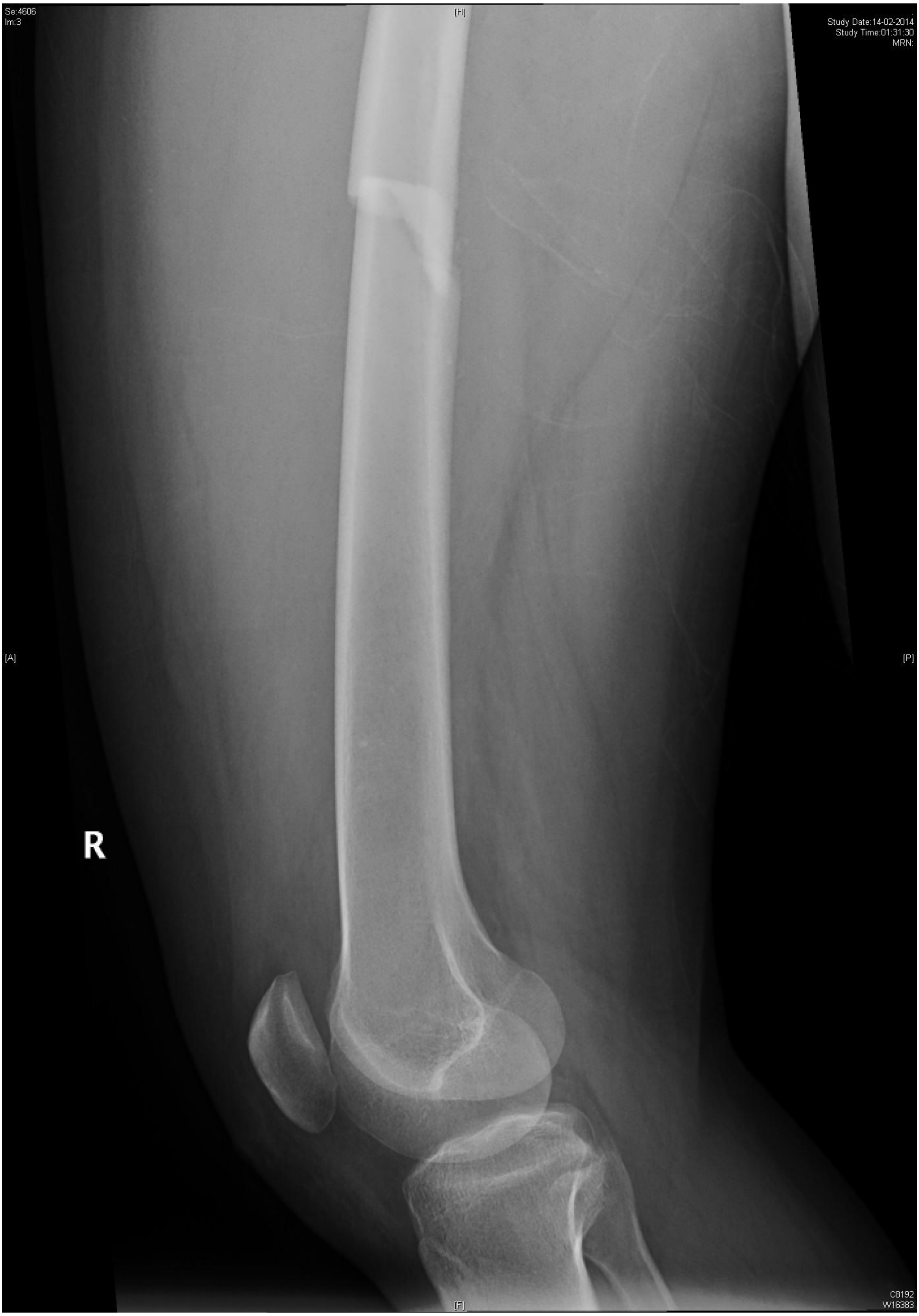


Figure 8 - Winquist and Hansen type 1

Figure 9 - Winquist and Hansen type 2

Figure 10 - Winquist and Hansen type 3

Figure 11 - Winquist and Hansen type 4

The amount of comminution can be correlated with the chances of malrotation and shortening. Grade 3 and 4 comminution is more prone to malunion than grade 1 and 2 and also determine the modality of fixation to be used.(48)

REVIEW OF RANDOMISED CONTROL TRIALS

In this segment we review a few of the randomised control trial that have been undertaken for femoral shaft fractures

Bar-On et al in 1997 presented 20 femur diaphyseal fractures, between the ages 5-15, type I or II open or closed which they randomised 10 each into Flexible intramedullary nailing or External fixation (Orthofix or AO External fixation). They reported that in the early postoperative period, healing course was similar, but more callus formation was seen with the FIN group. The time to full weight-bearing, full range of movement and return to school were all shorter in the FIN group as was the patient satisfaction and so they advised usage of FIN for the fixation of femur diaphyseal fractures. (49)

Malo and associates in 1999 published a trial with 43 fractures in the ages 5-13 years. They gave initial traction for both groups, 15 of those went into a functional brace while the other 28 had spica casting. These were followed up after a minimum of 5 years and they looked for unacceptable malunion. They found that the results in the two groups were comparable and that functional bracing was a good alternative for spica casting.

A single centre randomised trial was published in 2002 by Domb with 53 femur diaphyseal fractures. Children from the age groups of 3 -12 years were included. The hypothesis tested was that a dynamic external fixator led to faster healing rates as compared to a static external fixator. Their conclusion was that though there was early callus formation in the dynamic fixator group , the radiographic union happened faster in the static fixator group by 1 week which was not statistically significant.(50)

Hsu et al in 2009 presented their finding in 51 children between 5 and 12 years with diaphyseal fracture in a resource limited setting and compared dynamic skeletal traction and spica casting versus elastic intramedullary nailing. They found that although the hospital stay and the cost of procedure was higher for the elastic nailing group, the radiographic measurements were similar in both groups.(51)

Wright et al in 2006 published a multicentre trial including 108 children with femoral fractures and compared immediate hip spica with external fixation. They got children between age groups of 4 and 10 years and got 60 patients in the spica and 48 in the Orthofix external fixator group. They found that 6 children in spica group had unacceptable loss of a reduction and had to be treated with other methods. In the external fixator group, 2 had re-fractures, while 5 had to undergo fixator adjustment. There was significantly higher malunion rates in the spica group and they found external fixators to be a better modality of treatment .They advised further trial for comparison of nailing to external fixators.(22)

Medhinasab and associates in 2008 compared open reduction and intramedullary pin fixation with skeletal traction by 90-90 technique followed by spica in seventy patients in the 6 -11 year age group and found good outcomes with the intramedullary fixation. Shemshaki also compared similar modalities – Titanium elastic nailing and Skeletal traction followed by hip spica casting in 23 children in each arm and found significantly better results with nailing in terms of hospital stay, time to walk, weight bearing and functional scoring.(52)

In a systematic review of all the randomised and quasi randomised trials that were published till May 2014, Madhuri et al concluded that there was insufficient evidence to establish superiority of one conservative method to another (51). External fixation resulted in lower malunion rates than hip spica and titanium elastic nail reduced time to return to activity and it was the method with the highest patient satisfaction. They suggested further studies be conducted to remove the uncertainty about the treatment modality of choice for these fractures. (53)

RATIONALE FOR THE STUDY

Femoral fractures in children present a special problem and there are a variety of treatment options; Pavlik harness up to 18 months, spica cast till the age of five years are accepted forms of treatment. These should be followed up with careful attention to detail, as complications are known to occur. Surgical treatment is superior in older, larger children and adolescents, in multiple fracture situations, pathologic fracture, open fracture and obesity. TENS is currently preferred treatment for middle 2/3 femoral shaft fractures, provided the weight of the child is less than 50 kg.

Plating for femoral fractures, despite being an established mode of treatment in adults, is not popular in paediatric practice. Elastic stable intramedullary titanium nailing (ESIN) is currently the most popular treatment option in paediatric femoral fractures.

Previously, non operative treatment with traction and spica casting was used for most of the fractures but now this is limited to the age group up to 5 years and has been found to have multiple complications for the older children.(54) Operative treatment is becoming the norm for femoral fractures in children older than 5 years of age.(55) There are various modalities for operative treatment. External fixation using pins in the bone connected to rods outside the body has been found to have most complications and is now limited to fractures in which the bone fragments have come to lie exterior or there is extensive skin damage.(56) Other methods are putting two thin titanium nails less than half the diameter of the femur shaft inserted through the distal portion of the bone (ESIN) or putting a plate and screw over the bone directly(sub muscular plating) and rigid nailing in older children who have completed most of their growth.(57) Elastic nailing was the previous treatment of choice with good results but recent studies (58) have reported suboptimal results with elastic titanium nails for femoral fractures. Narayanan and Sink et al have reported higher complication rate and risk of unplanned surgery in length unstable fractures. After introduction of the locked plating technique, plating for femoral fractures is again come to the fore as a viable option in children. The results of biological plate fixation were found to be very good and there are a few studies that have retrospectively looked at the union and complications of the femoral plating and compared it with nailing, spica and traction and external fixation (other modalities of treatment for femur diaphyseal fractures). Compression plating was done earlier with large incisions and the results were not optimal. (10) This method currently is not very popular but after introduction of the sub muscular plating technique in which small incisions are made to slide the plate under the muscle over the bone and small incisions are done to apply the screws (59–61) promising results have been achieved especially for complex or multifragmentary fractures. (54,56,62)

In a study of 39 paediatric femoral fractures stabilized with elastic nail, Sink et al (63) classified fracture patterns as length-stable or length-unstable; transverse or short oblique fractures were considered length-stable, whereas long oblique, long spiral or comminuted fractures were classified as length-unstable. An oblique fracture is considered long if the length of the fracture is twice the diameter of the femoral shaft at that level. The authors found that unstable fractures were more likely to require unplanned surgery than stable fractures (40% versus 8%, respectively). In the unstable fracture group, all of the unplanned surgeries involved shortening or removal of prominent or exposed nails that occurred as a result of fracture shortening or angulation. Shortening or angulation was more common in the unstable fracture group than in the stable fracture group (67% versus 13%, respectively). Use of a single-leg spica cast did not reduce complications. The authors recommended considering other methods of fixation for management of length-unstable fractures. Narayanan et al (55) reported similar findings in a series of 79 paediatric femur fractures treated with TENS. Loss of reduction and/or malunion was five times more likely in comminuted fractures that involved >25% of the femoral shaft. The authors recommended careful monitoring of these fractures and suggested that additional external immobilization may be beneficial.

The patient's weight and age can also affect the outcome of elastic nail fixation of pediatric femoral fractures. In a study of 230 diaphyseal femur fractures managed with ESIN fixation, Moroz et al (9) found that patient weight >49 kg was associated with a fivefold increased risk of poor outcome. The authors also found a greater risk of poor outcome in older children than in younger children with femoral shaft fractures treated with elastic nail fixation. Children aged ≥11 years were nearly four times more likely to have a poor outcome than children younger than 11 years.

Kanlic et al (42) were the first to publish results on sub muscular plating of complex pediatric femoral fractures. In a study of 51 patients (average age, 10 years; average weight, 38.2 kg) with complex femoral fractures, treated with sub muscular plating, more than half of the patients had unstable fractures, 6% had distal third fractures of the femur, and 24% had subtrochanteric fractures. Following plating, no postoperative immobilization was used. In addition, no nonunion, wound healing problems, infection, or clinically significant rotational or angular deformity was reported. Four patients developed limb-length discrepancies ranging from 23 mm shorter to 10 mm longer than the uninjured side. All patients returned to their previous levels of activity with no symptoms. Based on these findings, the authors suggested that sub muscular plating may be beneficial for comminuted and spiral fracture patterns and for proximal and distal third fractures of the femur. Postoperative immobilization is unnecessary following sub muscular plating of these difficult fractures. Kanlic et al reported good results with sub muscular plating of complex femoral fractures in children up to age 15 years and in those who weighed up to 72 kg. This technique is especially useful if the patient's femoral canal is too narrow to accept a rigid IM nail.

Sink et al (60) reviewed 27 pediatric patients with comminuted and long oblique femoral fractures treated with sub muscular plate fixation. Average patient age was 9 years; 8 patients were aged 13 to 15 years. One patient developed sagittal angulation >10° with no clinical morbidity. No patient developed angulation >10° in the frontal plane. Maximum limb-length discrepancy was 5 mm. Outcome measures associated with plate fixation included average length of hospitalization (3 days), time to callus formation on radiographs (5.4 weeks), time to union (11.7 weeks), and time to unsupported weight bearing (10 weeks) and were comparable to those associated with elastic nail fixation. In addition, no unplanned surgical procedures or implant failures were reported. Older children (aged 13 to 15 years) did not have a higher rate of complications. The authors found sub muscular plating to be a successful alternative to IM nailing with elastic nail for management of complex femoral fractures including length-unstable fractures, proximal and distal fractures, and fractures in older children.

Plating has been found to be biomechanically more stable and stronger. Porter et al (64) while comparing the mechanical stability of unstable pediatric diaphyseal femur fractures fixed with titanium flexible intramedullary nails or a titanium locking plate using a synthetic femur model found that the modulus for comminuted and oblique fractures measured during the application of axial compression loading and the yield point for comminuted fractures and oblique fractures was significantly higher for plate constructs.

There are many retrospective studies proving plating to be equally good as nailing if not better. This study was undertaken to test the hypothesis prospectively that sub muscular plating is a superior method of treating diaphyseal femur fractures in children than elastic stable intramedullary nailing.

MATERIAL AND METHODS

The Study was conceived in the Department of Paediatric Orthopaedics after carefully going through the literature and finding insufficient data for the optimal treatment choice in paediatric femoral fractures.

The following study design was put forward to the Institutional Review board on August 31 2013

i. Intervention and Comparator agent: Randomized control trial comparing submuscular locked compression plating (intervention group) with elastic stable intramedullary nailing (comparator group).

ii. Key Criteria

   a. Inclusion Criteria:

      a) Diaphyseal fractures of femur (upper limit starting below lesser trochanter and distal limit decided by Muller square)

      b) Ages 5-15 years

   b. Exclusion Criteria:

      a) Previously operated cases

      b) Any other injury which will interfere with further rehabilitation

      c) Head injury (Glasgow coma scale less than 11)

      d) Pathological fracture

      e) Open fracture

iii. Method of randomization: Computer generated randomization sequence generated by the statistician.

iv. Method of allocation concealment: Opaque sealed envelopes kept in operating room opened once the consent is signed.

v. Blinding and masking: since this an surgical interventional trial operator and assessor blinding is not possible

i. Primary Outcome:

i. Malunion - As per assessment at the end of 24 months and defined as one or more of the following:

a) >15° of angulation in the coronal plane (varus or valgus),

b) >20° of angulation in the sagittal plane (apex-anterior or apex-posterior angulation),

c) Clinically obvious malrotation (an asymmetric foot progression angle with corresponding asymmetry of internal or external rotation of the hip), or

d) Limb-length discrepancy of >2.0 cm

ii. Serious adverse effects

a) Non-union defined as remodelling (mature) callus bridging less than three of the four cortices seen on two orthogonal views of the femur

a) Infection deep surgical wound infection

b) Reoperation: Defined as any fracture-related procedure, other than routine hardware removal, performed after the initial fixation.

c) Nerve injuries,

d) Compartment syndrome,

e) Decrease Range of Movement (ROM) in proximal and distal joint as compared to the opposite side

f) Implant related complications

iii Functional outcome measures using Paediatric outcomes data collection instrument (PODCI) at the end of 6 months, 12 months and 24 months.

vii Secondary Outcome/s:

i. Time for return to usual activity(school and play):
ii. Hospital bill
iii. Duration of surgery
iv. Amount of intra-operative blood loss
v. Amount of radiation exposure
vi. Time to union
vii. Hospital stay

Target sample size and rationale: Using the study (65)

Li Y, Heyworth BE, Glotzbecker M, Seeley M, Suppan CA, Gagnier J, et al. Comparison of titanium elastic nail and plate fixation of pediatric subtrochanteric femur fractures. J Pediatr Orthop. 2013 May; 33(3):232–8.

. Sample size was calculated as two proportions were compared``

primary outcome _complications

Proportion in group I = .48

Proportion in group II = .14

Risk difference = 0.34

Power (%) = 80

Alpha Error (%) = 5

Side = 2

Required sample size for each arm = 28

Alpha Error (%)	Power (%)	Sample Size (n)
	70	35
1	80	42
	90	53

	70	22
5	***80***	***28***
	90	37
	70	17
10	80	22
	90	30

ii. Phase of trial: Phase 3

iii. Expected date of first enrolment: October, 2013

iv. Estimated duration of trial: 2 years

v. Protocol variations: Any rules for

a. interim analyses – at 1 year

b. For withdrawal of participants – the participants are free to withdraw at any time in the trial as they find fit.

c. For premature stopping of trial – in case of clinically significant difference in results between 2 modalities which may raise the evidence of harm in either group, the trial will be with held and scrutinized at interim analysis.

vi. Data monitoring committee - The committee was assigned and the trial underwent 1 data monitoring meeting in which it was suggested to follow up the patients at 2 and 4 months post operatively to ensure that there were no complications that went unnoticed.

The IRB approval was obtained at the end of September and recruitment started at the end of September. We were able to recruit 14 patients for the study till date and thus the data for 14 patients was calculated in this interim analysis.

Once a patient with femur fracture was identified in the emergency department, we were informed and he /she was enrolled into the study if the inclusion criteria was met. A written consent was taken from the parent and if the child was above 8 years of age, separate consent was taken from the child. An information sheet regarding both modalities and the risk and benefits of each was given to the parents and the child was admitted for operative intervention.

The randomisation envelope was then opened and the surgeon informed about the operative intervention meant for that patient. The mode of injury, the patient's age, the duration required to seek treatment were noted prior to the surgery.

All patients underwent operative management under the experienced hands of one of the Paediatric Orthopaedic doctors. The operative modalities were standardised and similar technique was used for all the patients. Intra-operatively, the type of reduction, the duration of surgery, the amount of blood loss and the amount of radiation exposure to the patient and the type of fracture according to Winquist and Hansen classification for the patient were recorded.

Post operatively, all patients were put on a knee brace for 2 weeks and ambulated non weight- bearing with crutches. The hip and knee joint were mobilised after the third post operative day. The patients were usually discharged on the 4^{th} or the 5^{th} post operative day. The sutures were removed 7-14 days post surgery in the outpatient department. The patients were regularly followed up at 2 and 4 months of surgery and the hip/knee movements was encouraged and assessed along with the signs of radiological and clinical union.

At 6 month follow up, the patients were administered the Paediatric Outcome Data Collection Instrument which is a comprehensive assessment of functional outcomes of any intervention in the paediatric musculoskeletal injuries. The six major categories assessed were the Upper extremity and physical function core scale, the transfer and basic mobility core scale, the sports and physical functioning core scale, the pain/comfort core scale, the happiness core scale and the Global Functioning core scale. The operative techniques and the PODCI scoring sheet have been attached in the annexure.

Also, at this point of time, limb length discrepancy, any malunion in the coronal, sagittal or rotational planes were looked for in the radiographs. Other minor complications such as infections, any implant related complications and nerve injuries were also recorded. The patients were to be followed up in this manner at 1 year and at 2 years post surgery.

An observational study was also carried out for comparison sake as significant trends were found during the course of the prospective study and also there was no sufficient data in the literature to compare the outcomes of the randomised trial.

From January 2012 to September 2013, consecutive patients with femoral fracture which were age matched between the nailing and plating groups were identified and included in the observational study. A Review of charts, outpatient and inpatient, with radiographs was done to analyse the following data.

- Age
- Area from which the patient hails from
- Mechanism of injury
- The side of femur injured
- The fracture type according to Winquist and Hansen classification
- The modality used for intervention - nailing / plating
- The duration of surgery
- The amount of blood loss intra-operatively
- The method of reduction of fracture
- The hospital bill incurred
- The total duration of follow-up
- Any malunion as previously described in the coronal, sagittal or rotational plane along with limb length discrepancy
- Any other serious adverse effect as previously described namely non-union, deep surgical wound infection, reoperation, Nerve injuries, Compartment syndrome,

Decrease Range of Movement (ROM) in proximal and distal joint as compared to the opposite side and Implant related complications as previously described

- Time to union

The minimum duration of follow up was the time taken for radiological and clinical union. The data was collected and cross checked by another person other than the primary surveyor and the data was tabulated.

The tabulation was done using Epidata version 3.1 which is a program for entering and documenting data supplied by the non-profit organisation “The EpiData Association” Odense, Denmark .

The analysis was done using SPSS statistical analysis tool version 16, which was released by Microsoft Corporation in 2007.

Statistical methods

Means and standard deviations of interval data were reported.

The baseline characteristics in the two treatment groups were compared by using analysis of variance for continuous data and Mann Whitney U test statistics for proportions. Analysis of variance was used to compare the mean lengths of the hospital stay and the time to union among the two treatment methods. Pair-wise comparisons of the two different treatment groups were performed for all the variables. Medians were reported for skewed data. Complications were reported as rates. Univariate analyses were performed with use of Mann Whitney U test.

Multiple logistic regression was planned but as there was no significant difference between the two groups and therefore could not be carried out. Significance was set at a two-tailed level of 0.05. As the numbers were small and did not fit into a normal distribution, the data was analysed using non parametric Mann Whitney U test instead of Pearson chi square or paired t tests.

RESULTS

CONSORT FIGURE

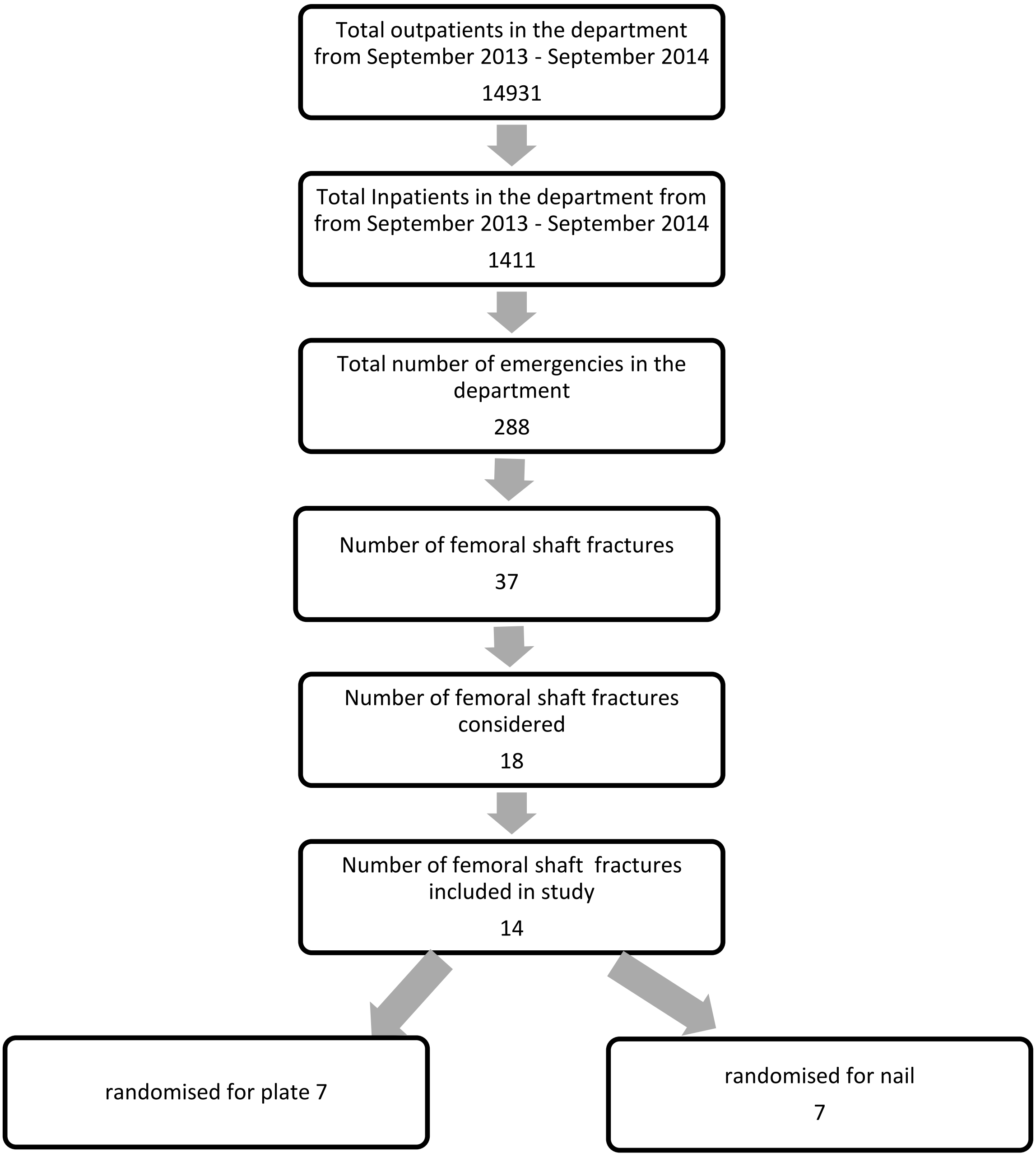


Figure12. **Showing the consort statement for the randomised control trial conducted in patients with diaphyseal femoral fractures between the age groups of 5-16 years who underwent Sub-muscular plating and Elastic Stable Intramedullary Nailing**

Table 1-5 - **Showing the baseline characteristics of the patients with diaphyseal femoral fractures between the age groups of 5-16 years who underwent submuscular plating and Elastic Stable Intramedullary Nailing**

Table 1 – **Ages of the patient across the nailing and plating groups**

modality used to treat the injury		N	Minimum	Maximum	Mean	Std. Deviation
PLATING	age of the patient	7	5	14	9.00	3.742
NAILING	age of the patient	7	5	14	8.71	2.812

The table shows that the patients have been equally randomised in both groups with near similar mean ages in each group.

Table 2 – **Distribution of patients according to sex across the nailing and plating groups**

modality used to treat the injury		Frequency	Percent
PLATING	Male	6	85
	Female	1	15
NAILING	Male	4	57
	Female	3	43

Table shows male predilection for the diaphyseal femoral fractures in both modalities.

Table 3 – **Area of the residence of the patient across the nailing and plating groups**

modality used to treat the injury			Frequency	Percent
PLATING	Valid	Vellore	4	57.1
		Rest of TN	3	42.9
NAILING	Valid	Vellore	5	71.4
		Rest of TN	1	14.3
		Other	1	14.3

The result shows that most of the patients included in the study were from Vellore or nearby areas

Table 4 – **Injured side of femur across the nailing and plating groups**

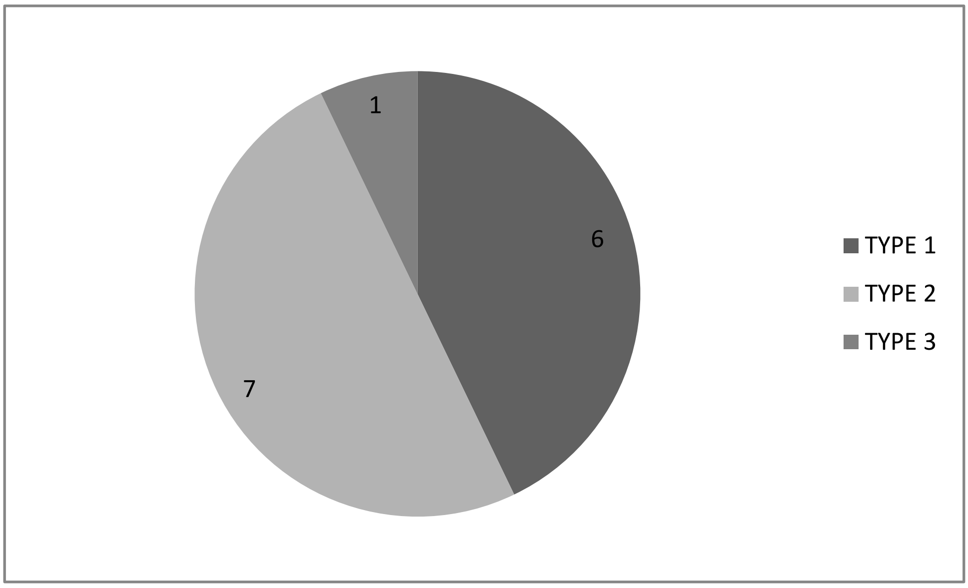
modality used to treat the injury		Frequency	Percent
PLATING	RIGHT	6	85.7
	LEFT	1	14.3
NAILING	RIGHT	4	57.1
	LEFT	3	42.9

The table reveals that 71 percent of all fractures happened on the right femur

Table 5 – **Mechanism of injury across the nailing and plating groups**

modality used to treat the injury		Frequency	Percent
PLATING	RTA	6	85.7
	FALL FROM HEIGHT	1	14.3
NAILING	RTA	7	100.0

This table reveals that almost all the fracture happened due to a road traffic accident



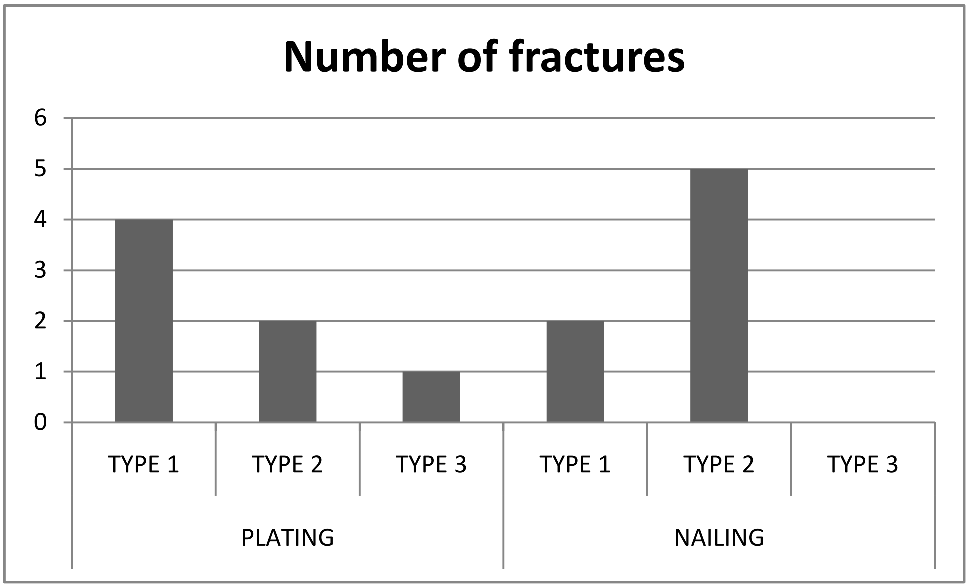


Figure 13-14 **Showing the type of fracture pattern according to Winquist and Hansen among the patients with diaphyseal femoral fractures between the age groups of 5-16 years who underwent Submuscular plating and Elastic Stable Intramedullary Nailing**

The figures show that 46 percent of the fractures were type 1 and type 2 respectively a total of 92 %. Only 7 % of the fractures were found to be type 3.

Table 6-10 **the prevalence of malunion among the patients with diaphyseal femoral fractures between the age groups of 5-16 years who underwent Submuscular plating and Elastic Stable Intramedullary Nailing**

Table 6 – **Malunion**

modality used to treat the injury		Frequency	Percent
PLATING	NO	4	100.0
NAILING	NO	4	100.0

Table 7 **- coronal angulation >15°**

modality used to treat the injury		Frequency	Valid Percent
PLATING	NO	4	100.0
NAILING	NO	4	100.0

Table 8 - **Sagittal angulation >20°**

modality used to treat the injury		Frequency	Valid Percent
PLATING	NO	4	100.0
NAILING	NO	4	100.0

Table 9 - **Clinically obvious malrotation**

modality used to treat the injury		Frequency	Valid Percent
PLATING	NO	4	100.0
NAILING	NO	4	100.0

Table 10 - **Limb length discrepancy >2 cm**

modality used to treat the injury		Frequency	Valid Percent
PLATING	NO	4	100.0
NAILING	NO	4	100.0

Tables 6-10 confirm the absence of any malunion found at the end of six months in either the plating or the nailing group.

Table 11-16 the presence of other serious adverse effects among the patients with diaphyseal femoral fractures between the age groups of 5-16 years who underwent Submuscular plating and Elastic Stable Intramedullary Nailing

Table 11 **Presence of infection among the nailing or plating group**

modality used to treat the injury		Frequency	Percent
PLATING	NO	7	100.0
NAILING	NO	7	100.0

Table 12 **Presence of nerve injury among the nailing or plating group**

modality used to treat the injury		Frequency	Valid Percent
PLATING	NO	7	100.0
NAILING	NO	7	100.0

There were no infections or nerve injury found among both the groups after operative management.

Table 13 **Incidence of compartment syndrome among the nailing or plating group**

modality used to treat the injury		Frequency	Valid Percent
PLATING	NO	7	100.0
NAILING	NO	7	100.0

Table 14**Incidence of implant related complications among the nailing or plating group**

modality used to treat the injury			Frequency	Valid Percent
PLATING	Valid	NO	7	100.0
NAILING	Valid	NO	7	100.0

Again the above tables reveal any absence of implant related complications or compartment syndrome among the 2 groups.

Table 15 **any revision surgery done among the nailing or plating group**

modality used to treat the injury		Frequency	Valid Percent
PLATING	NO	7	100.0
NAILING	NO	6	85.7
	YES	1	14.3

There was one patient in the nailing group who had a loss of reduction post surgery due to trivial fall and required closed reduction.

Table 16 **Incidence of joint stiffness among the nailing or plating group**

modality used to treat the injury		Frequency	Valid Percent
PLATING	NO	7	100.0
NAILING	NO	6	85.7
	YES	1	14.3

The same patient presented with knee stiffness at the end of six months.

Table 17 the normative scores for various groups using the PODCI scoring among the patients with diaphyseal femoral fractures between the age groups of 5-16 years who underwent Submuscular plating and Elastic Stable Intramedullary Nailing

The Normative score of 50 is considered to be normal – any score above 50 means that the patient is above the average functionality in that department.

modality used to treat the injury		N	Minimum	Maximum	Mean	Std. Deviation
PLATING	Upper Ext and Physical Fn Core Scale	4	57	57	57.00	.000
	Transfer and Basic Mobility Scale	4	53	53	53.00	.000
	Sports/Physical Functioning Scale	4	29	57	48.50	13.102
	Pain/Comfort Scale	4	55	55	55.00	.000
	Happiness Scale	4	40	57	52.75	8.500
	GLOBAL FUNCTIONING SCALE	4	49	58	55.25	4.193

NAILING		N	Minimum	Maximum	Mean	Std. Deviation
	Upper Ext and Physical Fn Core Scale	4	57	57	57.00	.000
	Transfer and Basic Mobility Scale	4	48	55	52.25	2.986
	Sports/Physical Functioning Scale	4	8	57	43.75	23.908
	Pain/Comfort Scale	4	28	55	47.75	13.200
	Happiness Scale	4	48	57	54.75	4.500
	GLOBAL FUNCTIONING SCALE	4	23	58	49.00	17.340

Mann-Whitney U	Upper Ext and Physical Fn Core Scale	Transfer and Basic Mobility Scale	Sports/Physical Functioning Scale	Pain/Comfort Scale	Happiness Scale	GLOBAL FUNCTIONING SCALE
p value	1.000	1.000	.882	.131	.850	.762

The sports and physical activity score were low accounting for less number of children going for professional sports. All scores were better for plating group. The upper Extremity and Physical function Core Scale and the Transfer and Basic Mobility Scale were more than 50 in both groups as these were not involved in the femur fracture which mainly affects the lower limbs. The Pain/Comfort Scale, Happiness Scale and Global functioning scale were directly affected by the femur shaft fractures but the children still achieve score over 5o in these categories in the plating group and near 50 in the nailing group, highlighting the excellent functional results got by each modality. The comparison of scores among the two groups was not statistically significant for any of the groups.

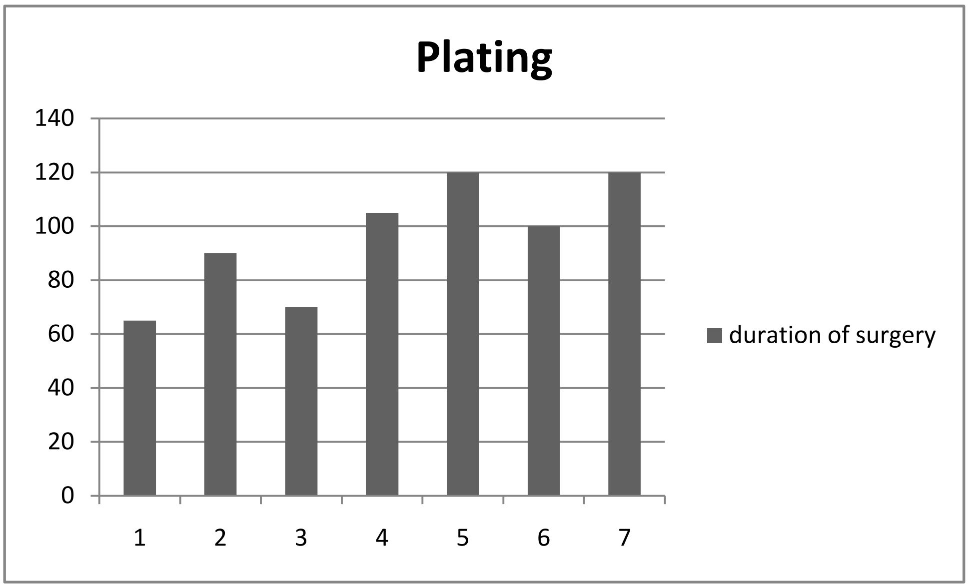
Table17 **Comparison of duration of stay, return to school and sports and time taken for union among the patients with diaphyseal femoral fractures between the age groups of 5-16 years who underwent Submuscular plating and Elastic Stable Intramedullary Nailing**

modality used to treat the injury			duration of stay(days)	return to school - duration weeks	return to sports - duration weeks	time taken for union(weeks)
PLATING	N	Valid	7	6	5	4
	Percentiles	25	4.00	8.00	11.50	9.50
		50	5.00	9.50	12.00	11.50
		75	6.00	10.50	14.00	12.00
NAILING	N	Valid	7	5	5	5
	Percentiles	25	3.00	7.00	11.00	9.50
		50	4.00	8.00	12.00	10.00
		75	5.00	15.00	19.50	16.50

Mann-Whitney U	duration of stay(days)	return to school - duration weeks	return to sports - duration weeks	time taken for union(weeks)
p value	.172	.249	1.000	.900

The median duration of stay for the nailing group (4 days) was 1 day lesser than the plating group (5 days). The median time duration for return to school was 9.5 weeks in the plating group as compared to 8 weeks for the nailing group but this was statistically not significant and the median time to return to sport was same for both the groups (12 weeks).

Similarly, the time taken for union was 1.5 weeks more for the plating groups but this was not statistically significant.



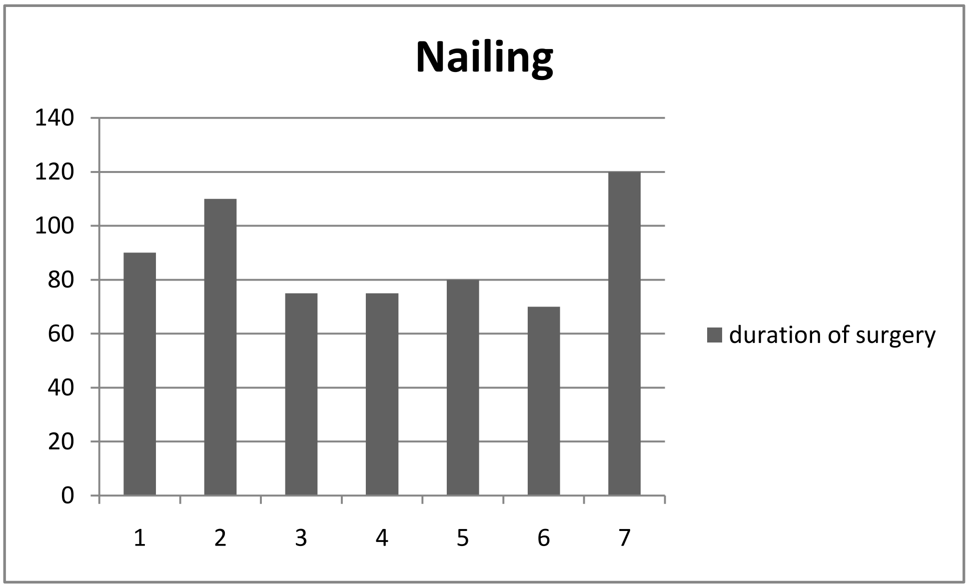
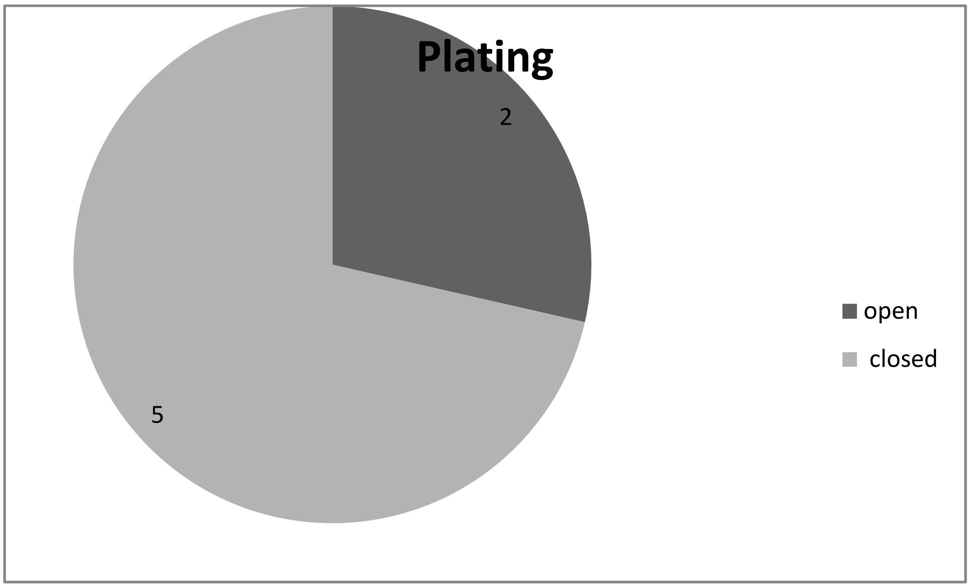


Figure 15-16 **Duration of surgery in minutes among the patients with diaphyseal femoral fractures between the age groups of 5-16 years who underwent Submuscular plating and Elastic Stable Intramedullary Nailing**

The median duration of surgery was 20 minutes lesser for the nailing group (80 minutes) as compared to the plating group (100 minutes) but this was statistically not significant (Mann Whitney U test p value 0.608)



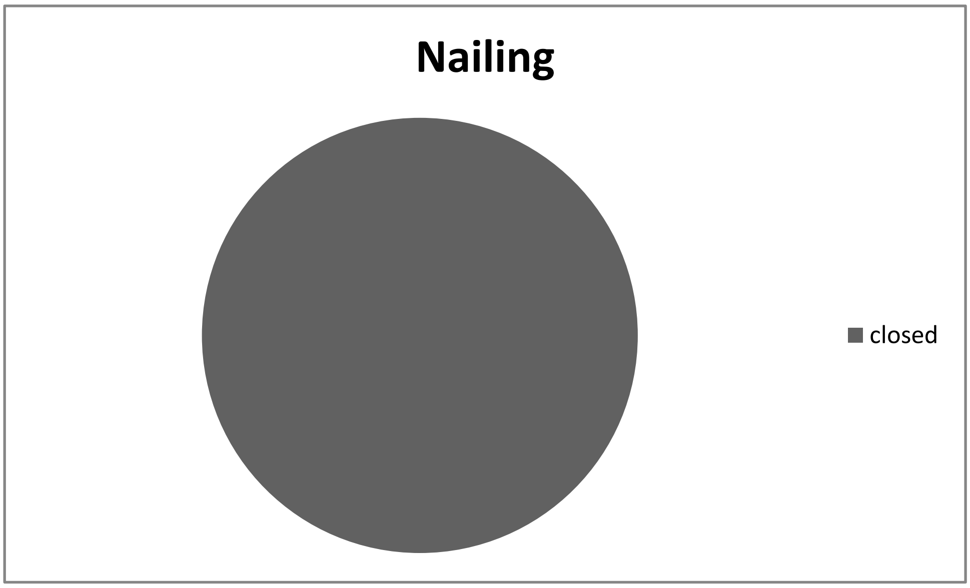


Figure 17-18 **Method of reduction among the patients with diaphyseal femoral fractures between the age groups of 5-16 years who underwent Submuscular plating and Elastic Stable Intramedullary Nailing**

All nailing patients and 71% of plating group patients underwent closed reduction

Table 18 **Comparison of total intra-operative blood loss among the patients with diaphyseal femoral fractures between the age groups of 5-16 years who underwent Submuscular plating and Elastic Stable Intramedullary Nailing**

modality used to treat the injury	N	Minimum	Maximum	Mean	Std. Deviation
PLATING total blood loss(ml)	7	30	250	107.86	77.828
NAILING total blood loss(ml)	7	50	150	85.71	37.796

Mann Whitney U test; p value- 0.846

The mean blood loss for plating group was 108 ml as compared to 86 ml for the nailing group. The standard deviation of plating group was 78 ml showing that a few cases accounted for the higher blood loss in the plating group. These could be the cases which underwent open reduction accounting for more blood loss. This difference was statistically not significant.

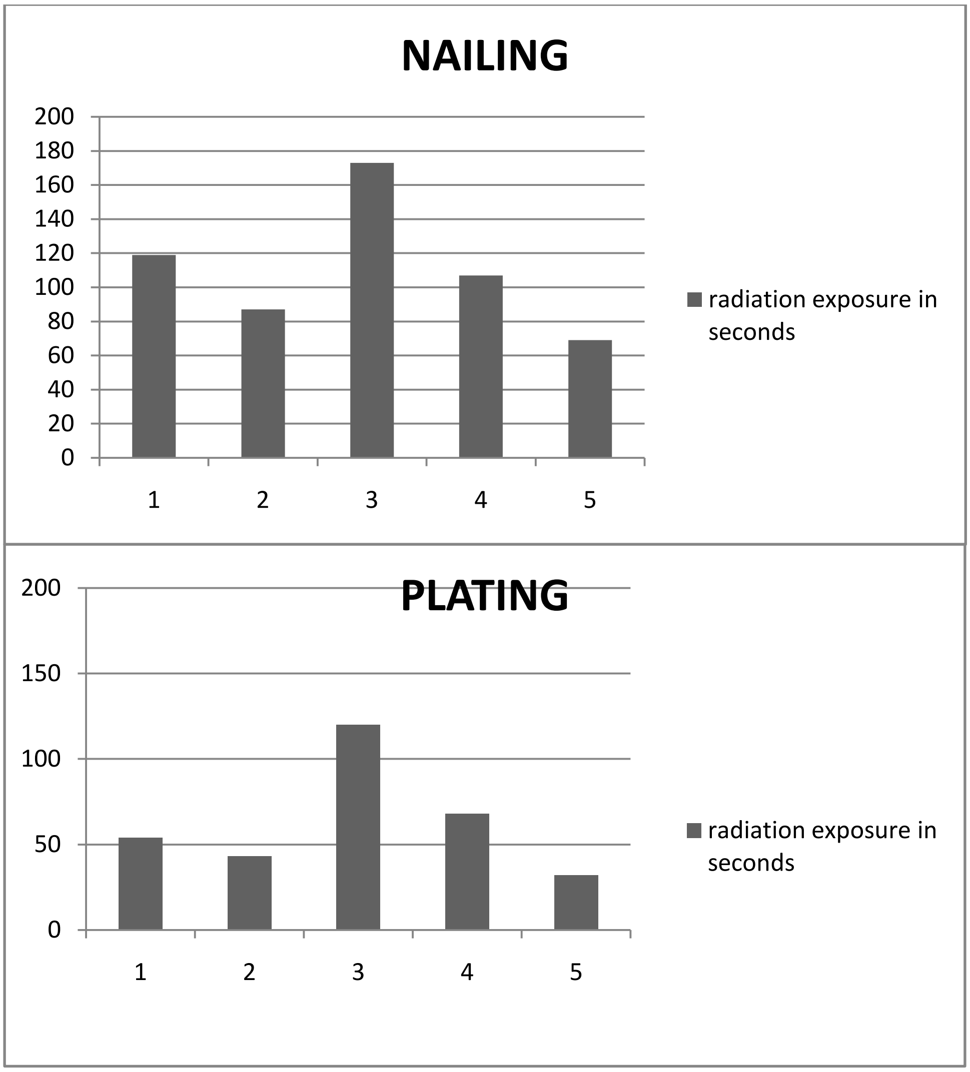


Figure 19-20, Table19 **Radiation exposure among the patients with diaphyseal femoral fractures between the age groups of 5-16 years who underwent Submuscular plating and Elastic Stable Intramedullary Nailing**

modality used to treat the injury		duration of radiation (seconds)
Plating	percentile 50	54.00
Nailing	percentile 50	107.00

Mann Whitney U test: p value - 0.076

Table 20 - **Mean hospital bill among the patients with diaphyseal femoral fractures between the age groups of 5-16 years who underwent Submuscular plating and Elastic Stable Intramedullary Nailing**

modality used to treat the injury		N	Minimum	Maximum	Mean	Std. Deviation
PLATING	hospital bill for the admission(rupees)	7	23886.00	50514.00	34553.2857	8218.12498
NAILING	hospital bill for the admission(rupees)	7	29439.00	45482.00	36784.4286	6033.64931

There was around 2000 rupee difference between the two groups with nailing costing more than the plating group.

The above results were for the randomised control trial group.

The following results represent the data collected in the observational study.

Figure 21 outcome of nailing in the randomised study group pre op anteroposterior and lateral views

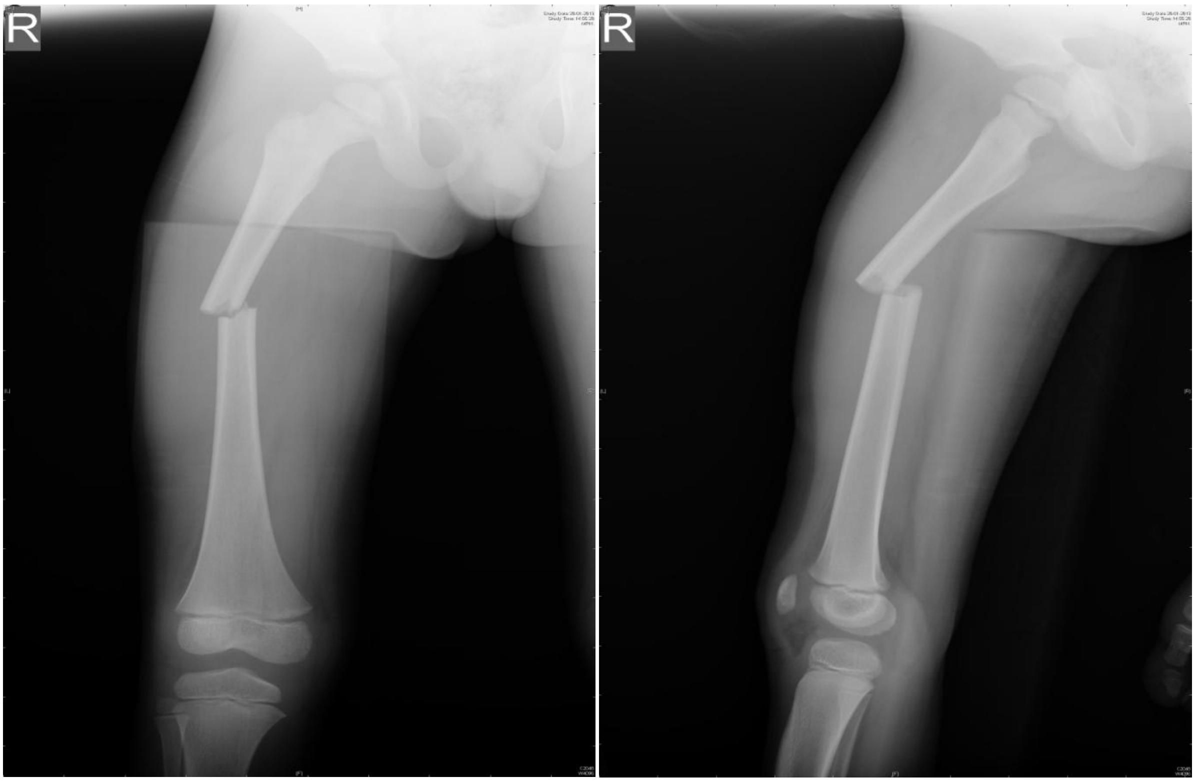


Figure 22 Post operative anteroposterior and lateral views

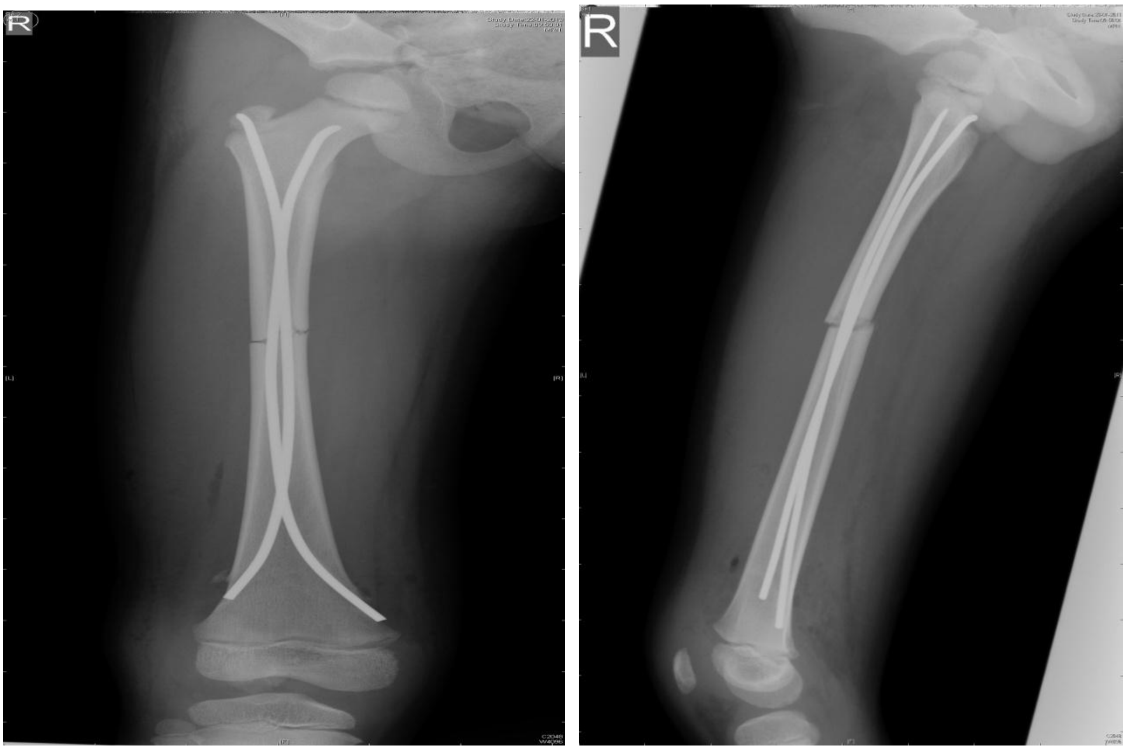


Figure 23 – Radiographs showing union in both views

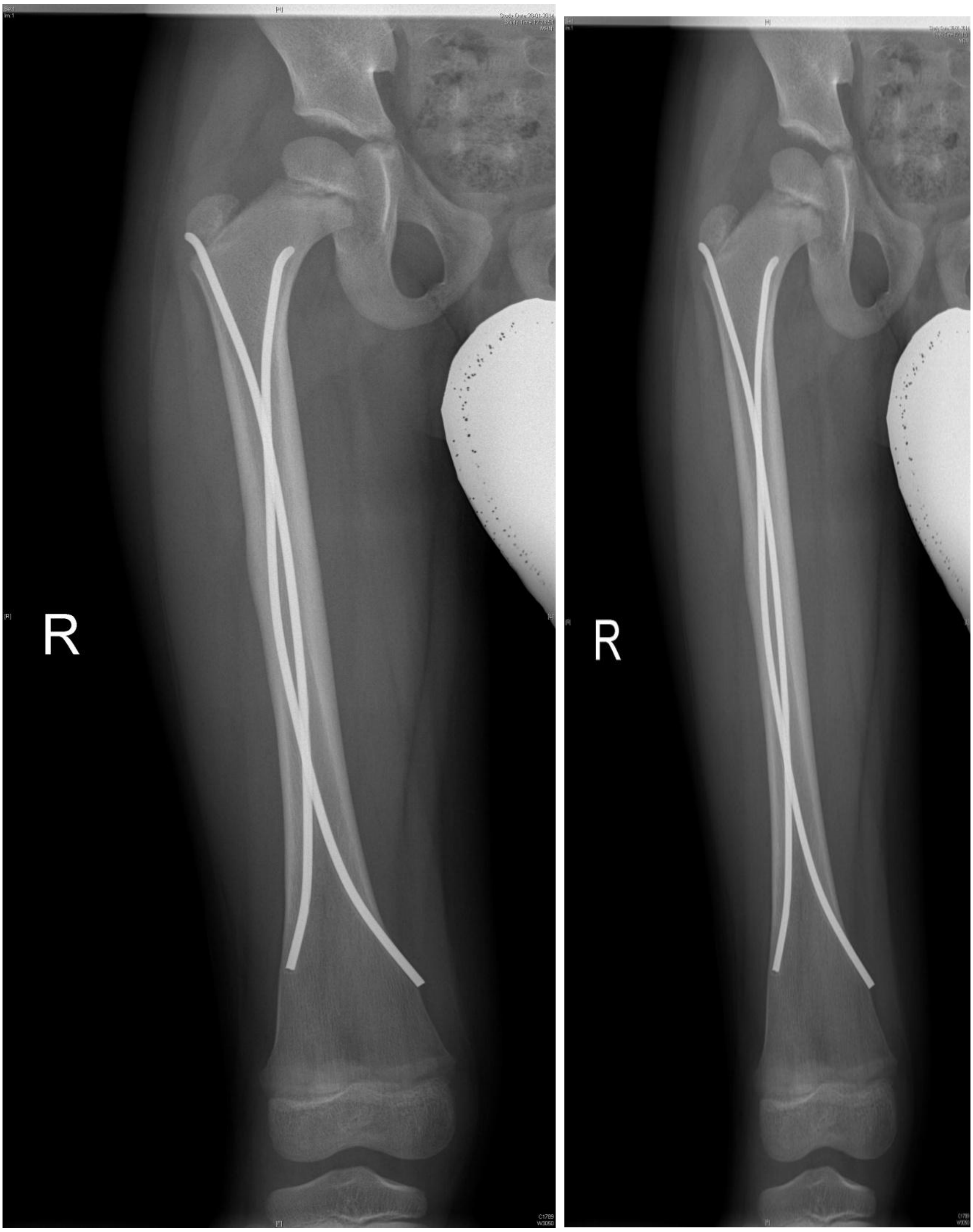


Figure 24 outcome of plating in the randomised study group pre operative anteroposterior and lateral views

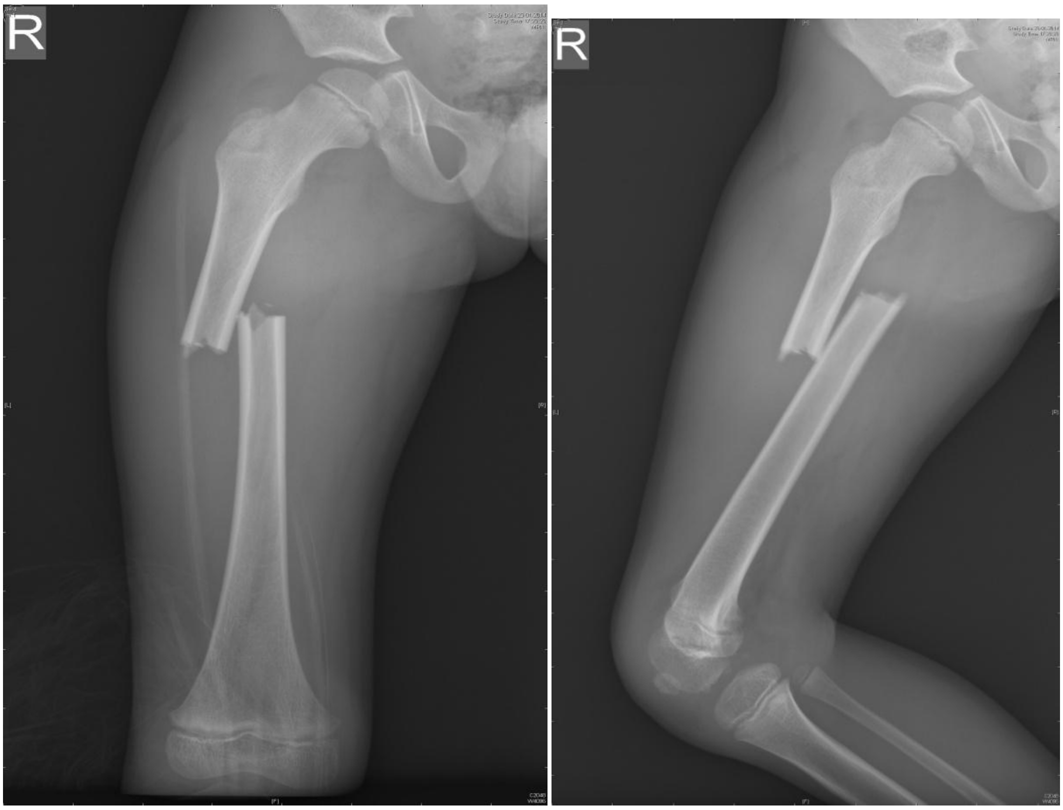


Figure 25 immediate post operative anteroposterior and lateral views

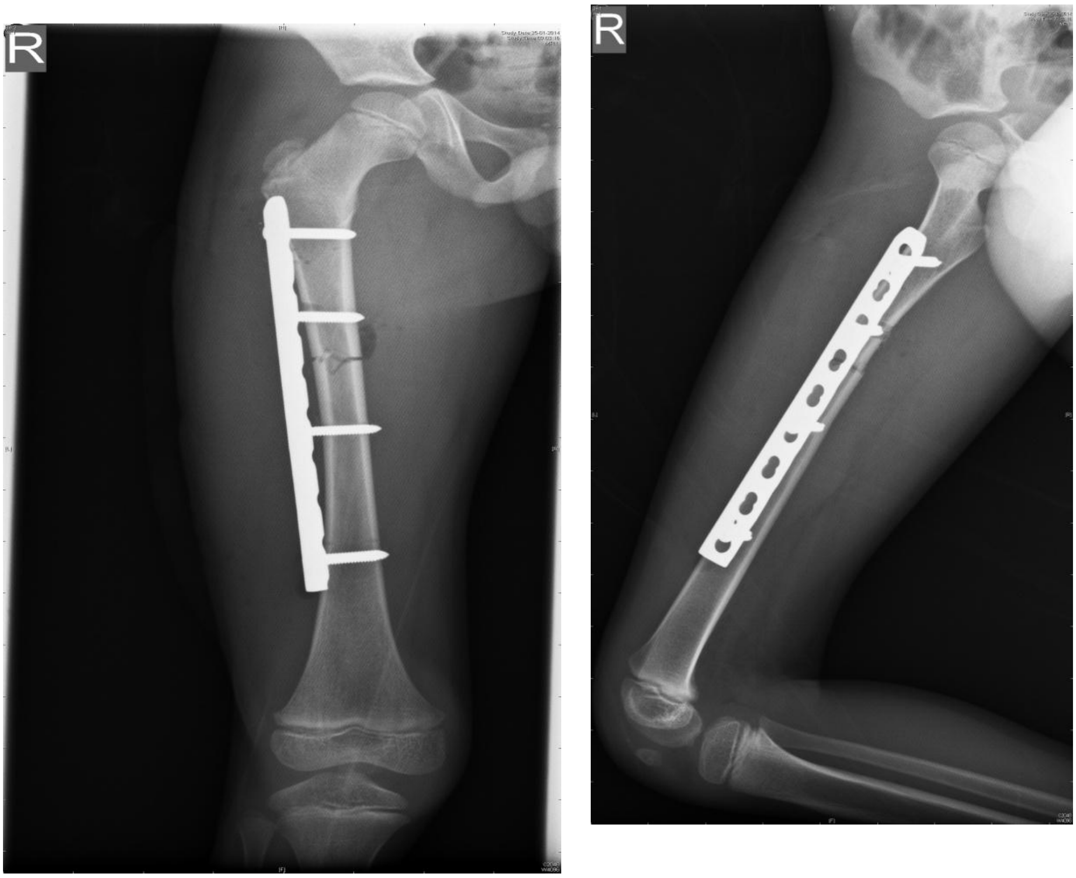
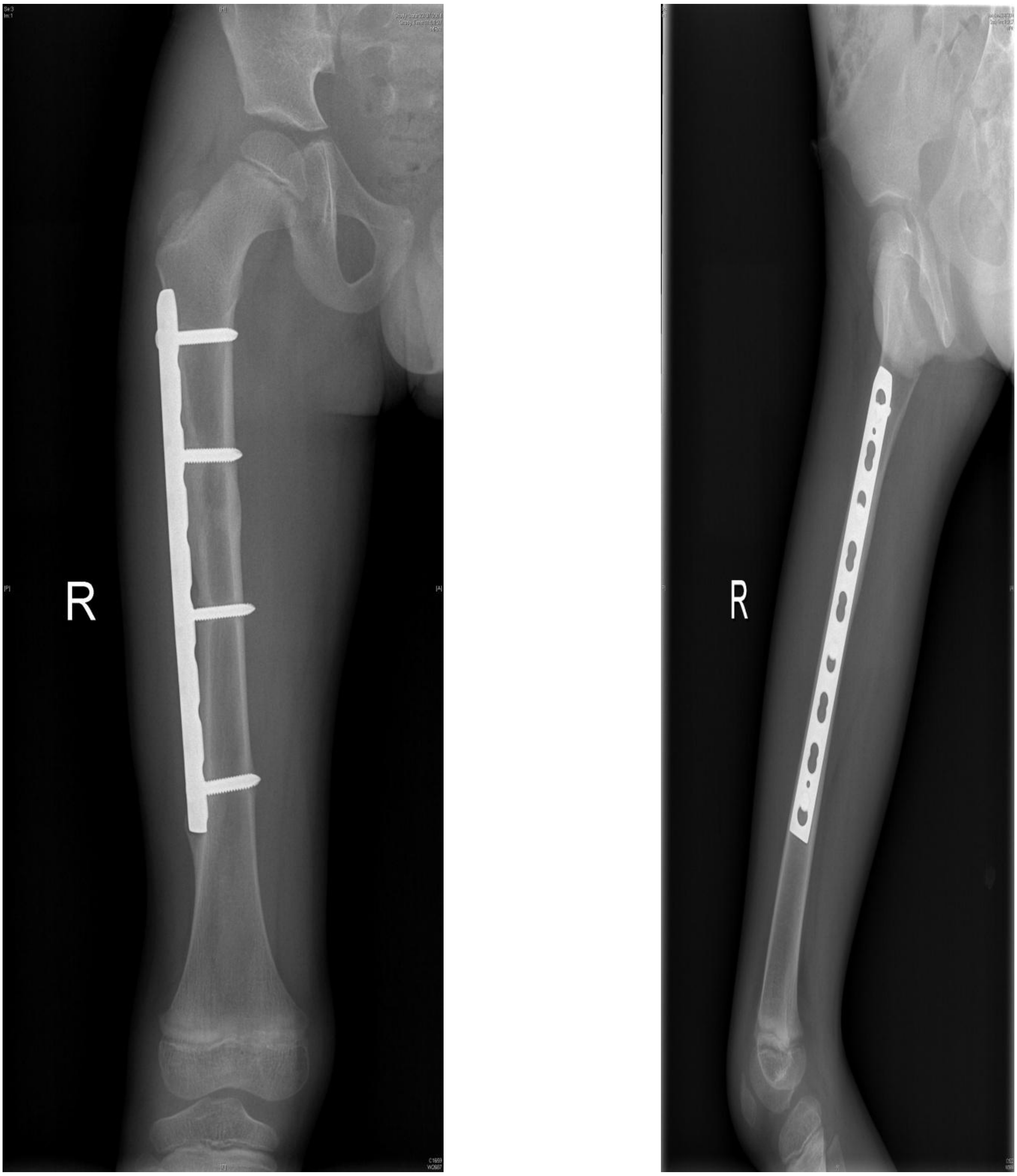


Figure 26 post union anteroposterior and lateral views



STROBE STATEMENT

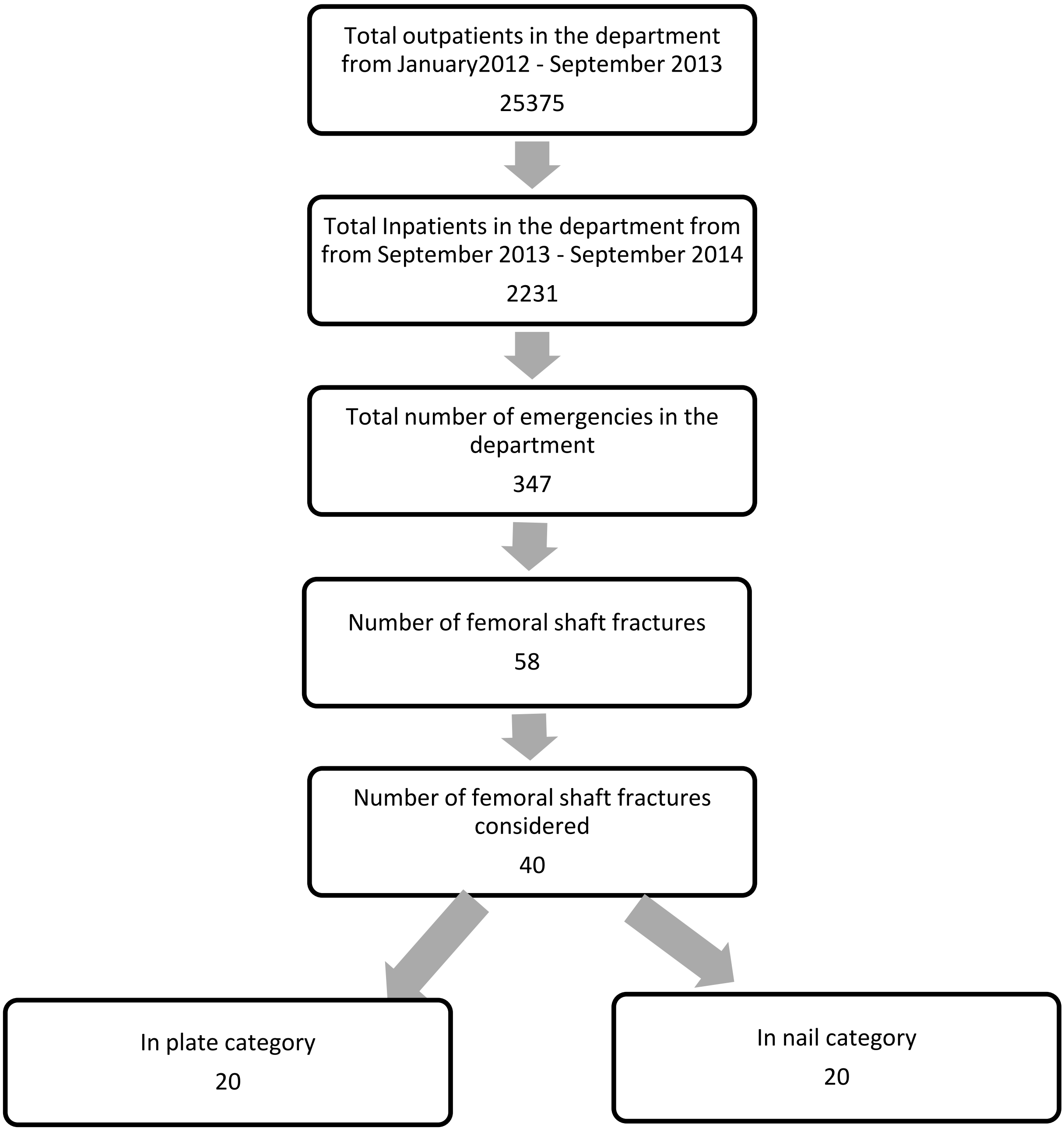


Figure 27 - **STROBE figure for the observational study conducted among the patients with femoral fractures between the age groups of 5-16 years who underwent Submuscular plating and Elastic Stable Intramedullary Nailing**

Table 21-25 **Baseline characteristics of patient with diaphyseal femoral fractures between the age groups of 5-16 who underwent Elastic Stable Intramedullary Nailing or submuscular plating showing mean ages and standard deviation**

Table 21 **Age of patients between the nailing and plating groups**

Mod		N	Minimum	Maximum	Mean	Std. Deviation
PLATING	age	20	5	16	11.25	3.477
NAILING	age	20	5	15	10.00	2.938

The mean age for plating group was 11.25 as compared to the 10 years for the nailing groups

Table 22 – **Distribution of patients according to sex across the nailing and plating groups**

modality used to treat the injury		Frequency	Percent
PLATING	Male	15	75
	Female	5	25
NAILING	Male	16	80
	Female	4	20

This shows a male predilection for femoral fracture with more than 75% children being male.

Table 23 – **Area of the residence of the patient across the nailing and plating groups**

Mod			Frequency	Valid Percent
PLATING	Valid	Vellore	8	40.0
		Rest of TN	8	40.0
		AP	3	15.0
		Other	1	5.0
NAILING	Valid	Vellore	13	65.0
		Rest of TN	4	20.0
		AP	2	10.0
		Other	1	5.0

The result shows that most of the patients included in the study were from Vellore or nearby areas. About 12% of all patients also presented from Andhra Pradesh

Table 24 – **Injured side of femur across the nailing and plating groups**

modality used to treat the injury		Frequency	Percent
PLATING	RIGHT	15	75.0
	LEFT	5	25.0
NAILING	RIGHT	14	70.0
	LEFT	6	30.0

The table reveals that 72 percent of all fractures happened on the right femur

Table 25 – **Mechanism of injury across the nailing and plating groups**

Modality used to treat injury	Mode of injury	Frequency	Valid Percent
PLATING	RTA	14	70.0
	FALL FROM HEIGHT	2	10.0
	OTHERS	4	20.0
NAILING	RTA	14	70.0
	FALL FROM HEIGHT	3	15.0
	OTHERS	3	15.0

This table reveals that 70 percent of all femoral fractures happened due to a road traffic accident. Another peculiar mechanism of injury was fall from height which constituted 12.5% of all femoral fractures. The other mechanisms include pathological fractures, peri-implant fractures and fall while playing.

Winquist and Hansen type 1 fractures were the most common type of fracture found in the paediatric age group.

More fracture of Winquist and Hansen type 3 and type 4 underwent submuscular Plating as compared to Elastic Stable Intramedullary Nailing. (35% vs 10%)

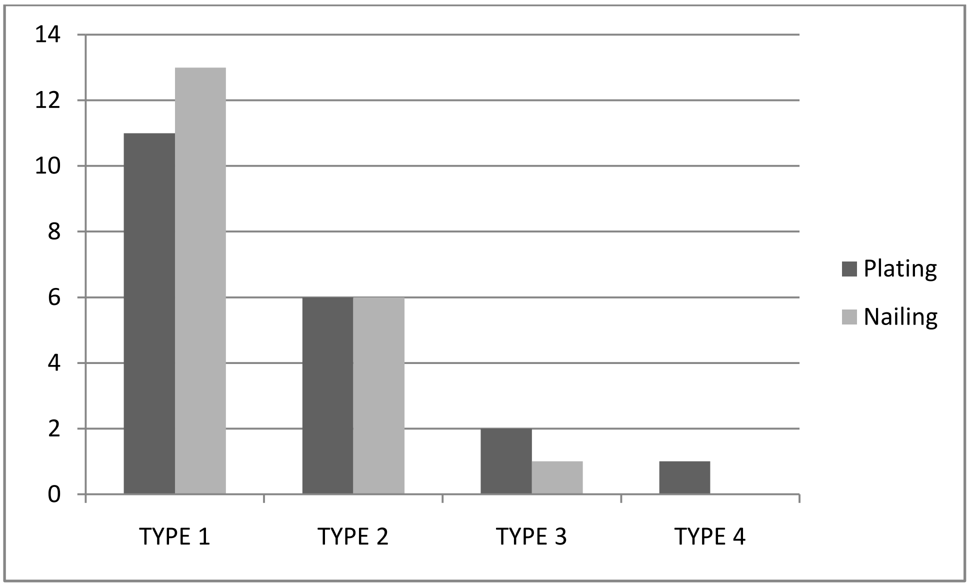


Figure 28 - **The type of fractures according to Winquist and Hansen classification for patients with diaphyseal femoral fractures between the age groups of 5-16 years who underwent Submuscular plating and Elastic Stable Intramedullary Nailing**

Table 26-30. Showing Malunion and the plane of malunion for patients with diaphyseal femoral fractures between the age groups of 5-16 years who underwent Submuscular plating and Elastic Stable Intramedullary Nailing

Table 26 - **Malunion**

Modality of treatment	Malunion	Frequency	Percent
PLATING	NO	18	90.0
	YES	2	10.0
NAILING	NO	19	95
	YES	1	5

The table reveals that there were 2 patients in the plating group (10 %) and 1 patient in the nailing group (5%) who were found to have malunion. This malunion was found to be in the coronal plane with varus angulation of more than 15 degrees in all the case. This has been elaborated in the following four tables.

Table 27 - **Coronal angulation >15 degrees**

Modality of treatment	Coronal angulation>20	Frequency	Percent
PLATING	NO	18	90.0
	YES	2	10.0
NAILING	NO	19	95
	YES	1	5

Table 28 - **Sagittal angulation >20**

Modality of treatment	Saggital angulation >20	Frequency	Percent
PLATING	NO	20	100.0
NAILING	NO	20	100.0

Table 29- **Clinically obvious malrotation**

Modality of treatment	Clinically obvious rotation	Frequency	Percent
PLATING	NO	20	100.0
NAILING	NO	20	100.0

Table 30 - **Limb length discrepancy>2cm**

Modality of treatment	LLD>2cm	Frequency	Percent
PLATING	NO	20	100.0
NAILING	NO	20	100.0

Table 31-33 The presence of other serious adverse effects among the patients with diaphyseal femoral fractures between the age groups of 5-16 years who underwent Submuscular plating and Elastic Stable Intramedullary Nailing

Table 31 - **Presence of infection among the nailing or plating group**

Mod			Frequency	Valid Percent
PLATING	Valid	NO	20	100.0
NAILING	Valid	NO	20	100.0

Table 32 - **Presence of infection among the nailing or plating group**

Mod			Frequency	Percent	Valid Percent	Cumulative Percent
PLATING	Valid	NO	20	100.0	100.0	100.0
NAILING	Valid	NO	20	100.0	100.0	100.0

Table 33 **Presence of compartment syndrome among the nailing or plating group**

Mod			Frequency	Percent	Valid Percent	Cumulative Percent
PLATING	Valid	NO	20	100.0	100.0	100.0
NAILING	Valid	NO	20	100.0	100.0	100.0

The above three tables show that there were no deep wound infections in any of the patients included in the study; also there were no instances of nerve injuries or compartment syndromes in the patients included in the observational analysis.

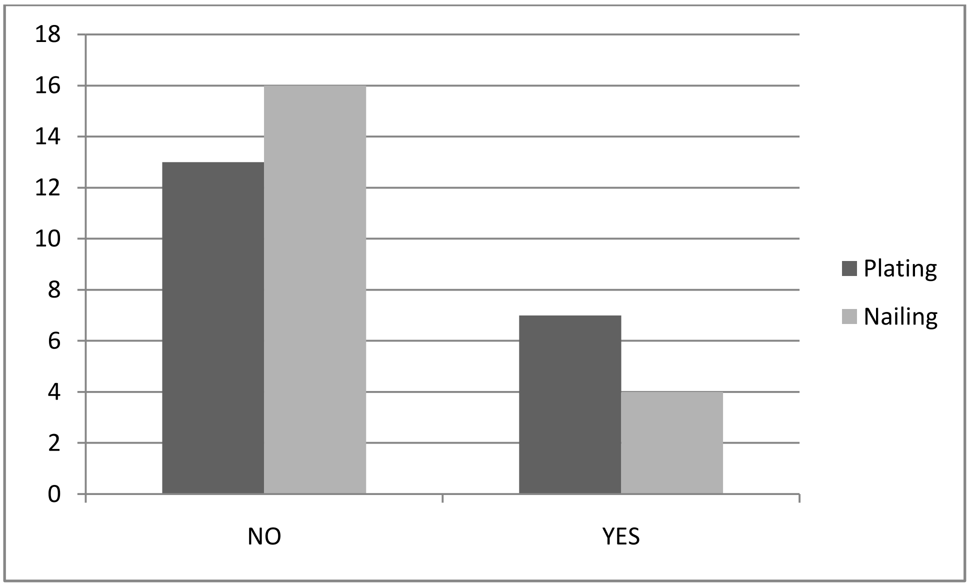


Figure 29 - **The number of revision surgeries undergone by the patients with diaphyseal femoral fractures between the age groups of 5-16 years who underwent Submuscular plating and Elastic Stable Intramedullary Nailing**

The figure shows that there were 7 revision surgeries for the plating group out of which 5 were elective implant exits and two for malunion. All 4 patients who underwent revisions in the nailing group were implant exits due to implant irritation.

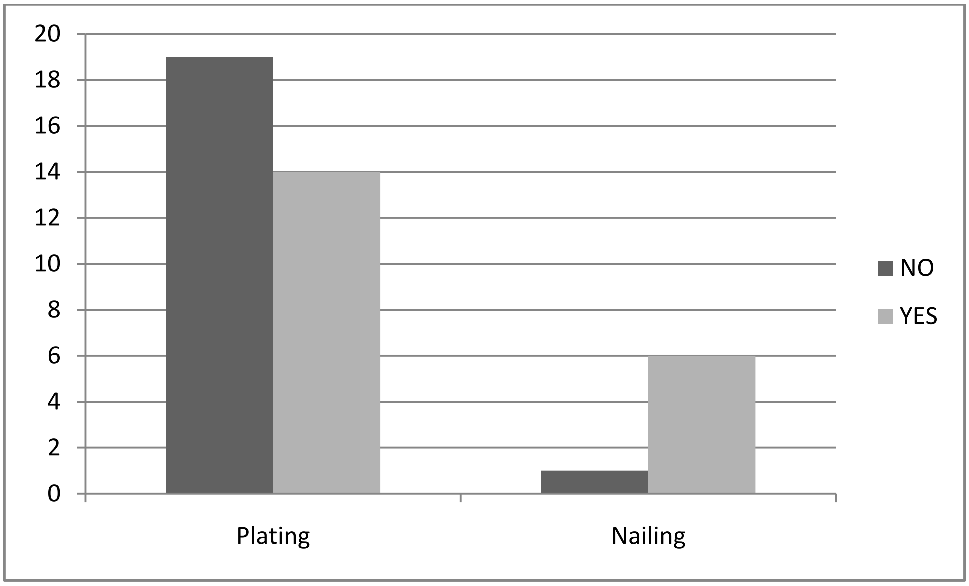


Figure 30 - **The number of implant related complications found in the patients with diaphyseal femoral fractures between the age groups of 5-16 years who underwent Submuscular plating and Elastic Stable Intramedullary Nailing**

There was only 1 implant related complication in which the plate bent, leading to malunion. There were 6 implant related complications in the nailing (30%) group, out of which 4 were due to nail tip irritation in the distal thigh region.

Table 34, 35 - **The presence of stiffness in the joints among the patients with diaphyseal femoral fractures between the age groups of 5-16 years who underwent Submuscular plating and Elastic Stable Intramedullary Nailing**

Modality of treatment	Stiffness	Frequency	Percent
PLATING	NO	20	100.0
NAILING	NO	19	95.0
	YES	1	5.0

Modality of treatment	Knee joint	Frequency	Percent
PLATING	NO	20	100.0
NAILING	NO	19	95.0
	YES	1	5.0

Decreased range of movement was found in a child in the nailing group (5%). The affected joint was the knee joint.

Table 36 - **The duration of surgery and the amount of blood loss among the patients with diaphyseal femoral fractures between the age groups of 5-16 years who underwent Submuscular plating and Elastic Stable Intramedullary Nailing**

Modality used for treatment			Duration of surgery	Amount of blood loss
PLATING	N	Valid	18	18
		Missing	2	2
		50	97.50	100.00
NAILING	N	Valid	20	20
		50	95.00	55.00

	Duration of surgery	Amount of blood loss
Mann-Whitney U	177.500	112.500
P value. (2-tailed)	.941	.043

In the Observational study the duration of surgery was similar for both the groups, 97.5 versus 95 minutes for plating and nailing respectively.

The amount of blood loss in the plating group was 100ml as compared to 55 ml for the nailing group. This difference was statistically significant.

Table 36 - **The duration of surgery and the amount of blood loss among the patients with diaphyseal femoral fractures between the age groups of 5-16 years who underwent Submuscular plating and Elastic Stable Intramedullary Nailing**

Modality of treatment	Percentile	Duration of stay (in days)	Follow up duration (in months)
Plating	50	6.00	12.00
Nailing	50	5.00	6.50

	Duration of stay	Follow up duration
Mann-Whitney U	145.500	142.500
"p"value (2-tailed)	.131	.118

The mean duration stay was 1 day more in the plating group as compared to the nailing group.

The follow up duration was almost 6 months more for the plating group than the nailing group and this was probably due to the complex nature of fractures that underwent plating and required longer monitoring.

Table 37- **The time taken for union among the patients with diaphyseal femoral fractures between the age groups of 5-16 years who underwent Submuscular plating and Elastic Stable Intramedullary Nailing**

Modality			Time to union (weeks)
PLATING	N	Valid	20
	Percentiles	50	12.00
NAILING	N	Valid	20
	Percentiles	50	10.00

The duration of time taken for radiographic and clinical union was 12 weeks for the plating group and 10 weeks for the nailing group. This can be explained according to the complex fracture patterns for which the plating modality was used.

Table 37- **Comparison of hospital bill among the patients with diaphyseal femoral fractures between the age groups of 5-16 years who underwent Submuscular plating and Elastic Stable Intramedullary Nailing**

Mod			cost
PLATING	N	Valid	20
	Percentiles	25	2.5600
		50	3.3300
		75	3.8500
NAILING	N	Valid	20
	Percentiles	25	2.7300
		50	3.3200
		75	3.9400

The hospital bill was minimally different between the two groups with median of Rs. 33300 for plating and Rs. 33200 for nailing. This also was statistically not significant (p value 0.882).

Figure 31 good outcomes in a case of bilateral femur fracture in the observational study group pre operative anteroposterior and lateral views

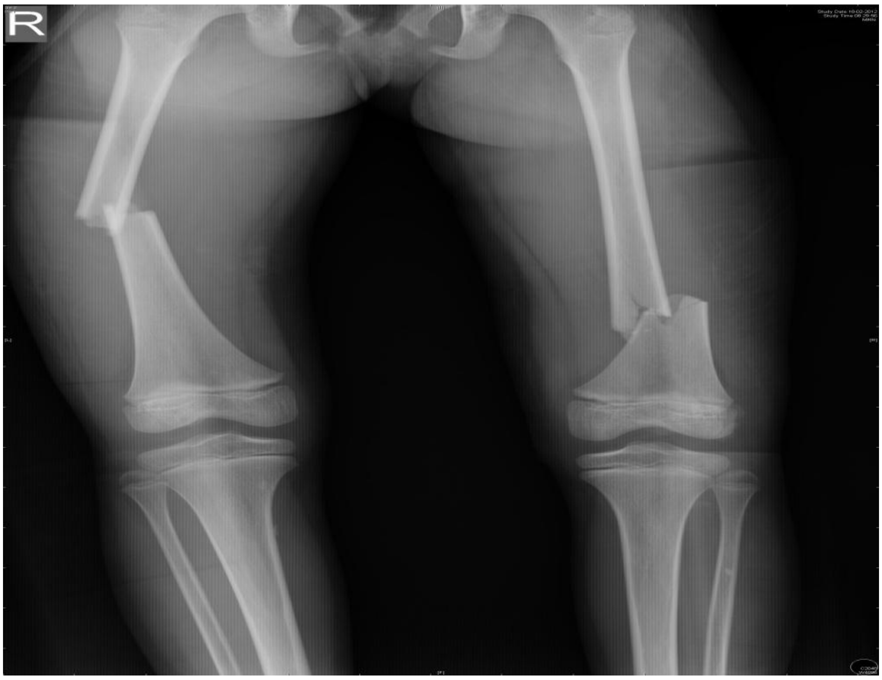


Figure 32 good outcomes in a case of bilateral femur fracture in the observational study group immediate post operative anteroposterior and lateral views

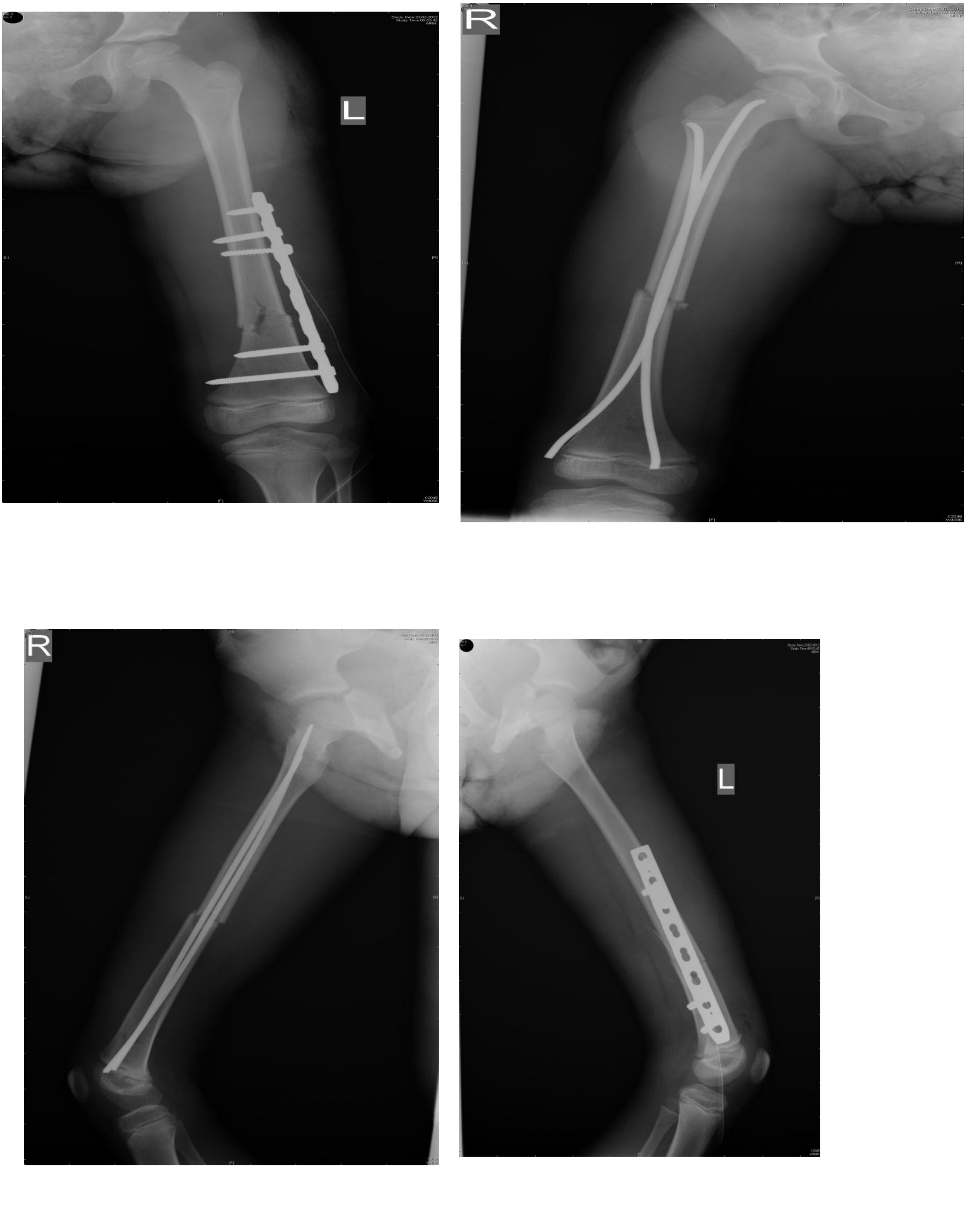
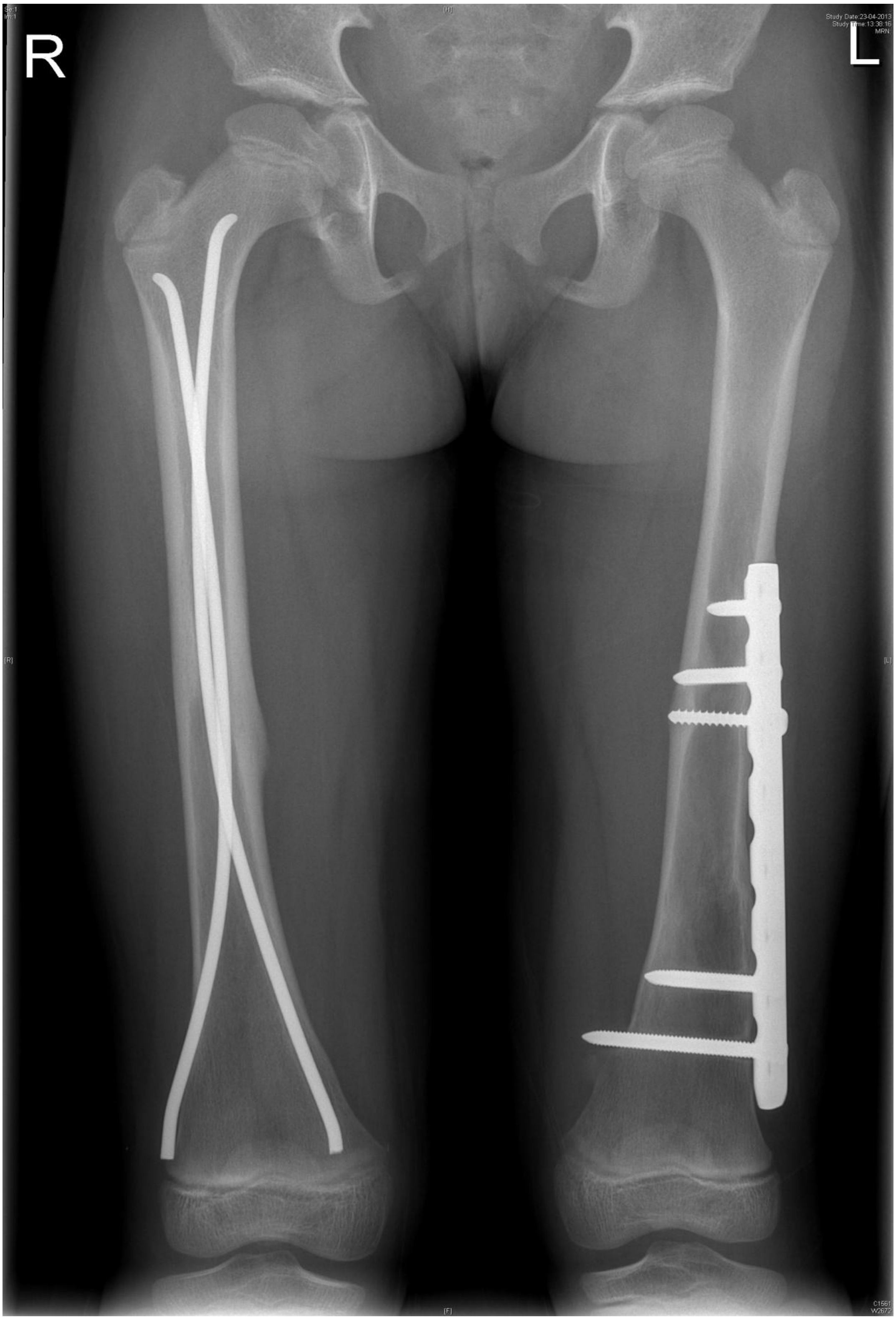
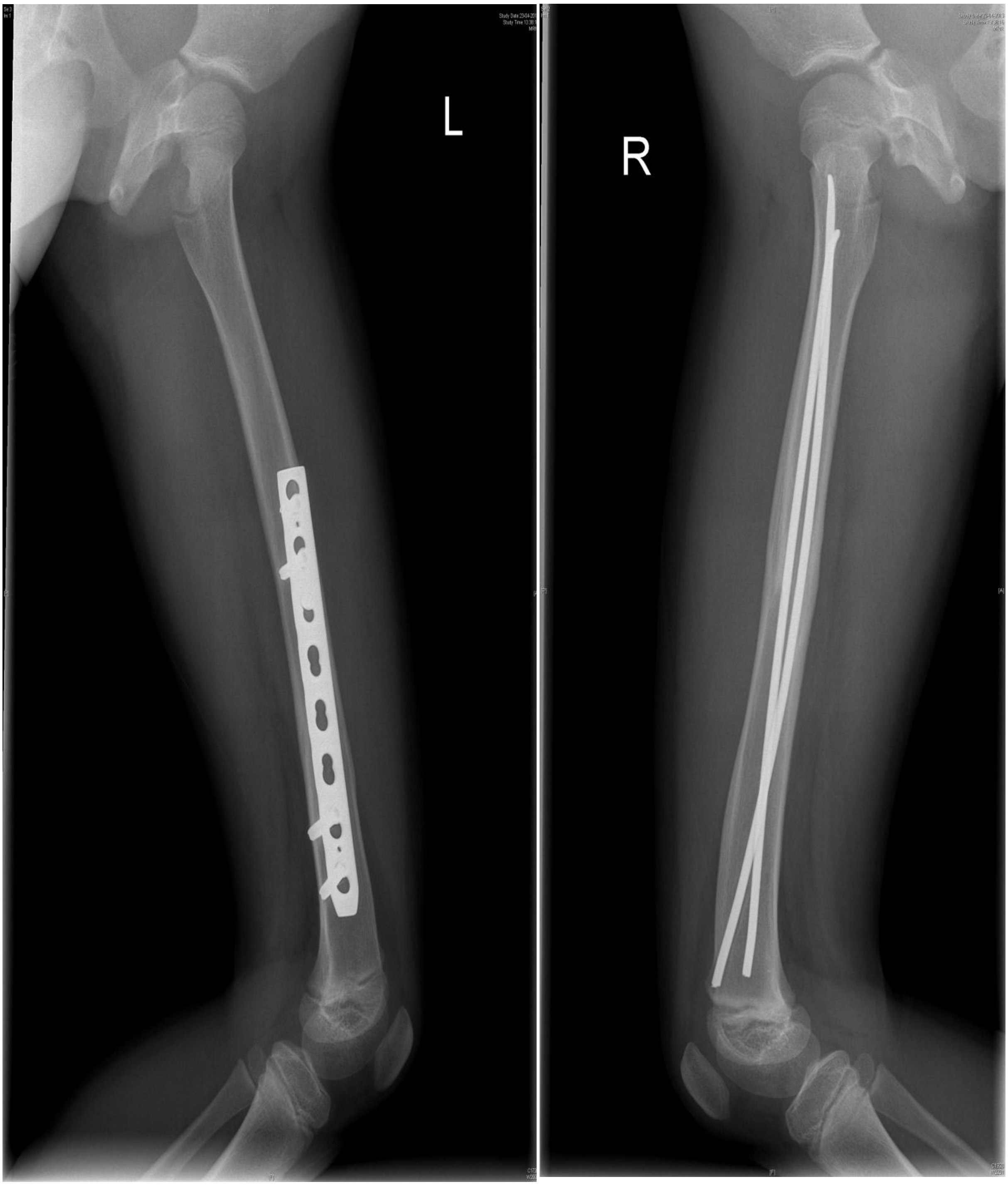


Figure 32 good outcomes in a case of bilateral femur fracture in the observational study group at the time of union anteroposterior and lateral views

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DISCUSSION

Paediatric femoral diaphyseal fractures though a rare occurrence (3% of all fractures) is a cause of serious morbidity for the child and the family in general. The treatment options for this fracture vary from traction, spica, external fixation to internal fixation using elastic nails, rigid nails and plates. Though these have been studied in some detail, the modality of choice and modality to use in which fractures is still obscure.

We conducted a study comparing the efficacy and outcomes of paediatric diaphyseal femoral fractures using submuscular locked plating and elastic stable intramedullary nailing between the age groups of 5-16 years.

We had two arms for the study one, a randomised control trial which enrolled children after screening through the exclusion criteria and randomised them to nailing or plating. We also conducted an observational study in the same age group of children to act as comparison to the results from the randomised control study.

This study is the first of its kind done for paediatric diaphyseal fractures in the age groups of 5-16 years in the Indian population.

We found that the mean age of patients in the nailing and plating group was 8.71 and 9 years respectively showing equal distribution of children across both arms. Also, there was no bimodal variation of fracture distribution according to age. The same holds true for the observational study but the mean ages were 10 and 11.25 years respectively, showing a predilection to use plating for the older children. This may be due to the fact that older children tend to have more weight and the velocity of injury is high leading to more number of comminuted fracture patterns in the plating arm. Literature has reports of poorer results with comminuted fractures using Elastic stable Intramedullary Nailing group. (66)

Most of our patients were from around Vellore in both the arms in the prospective study group whereas there were more patients from Andhra Pradesh and other areas in the observational study group which may point towards better availability of services in these areas in recent times.

The most common mechanism of injury in both the prospective trial (95%) and observational study(70%) were road traffic accidents which was consistent with the data found previously by many studies. (3,6) We didn't have a significant number of children having injuries due to contact sports as found in the western population as these are not popular in India. The stand out mechanism of injury for our population was fall from height e.g. fall from a tree was a common mode of injury.

Most of the fractures were Winquist and Hansen type1 or type2 fractures in both the prospective trial (93%) and observational study(90%) which is consistent with the data from prior studies. (6) In the observational study, more of type 3 and type 4 fractures were treated with submuscular plating (35 %) as compared to Elastic Nailing (10%). This was also reported by Sink et al in a study which said that length unstable fracture had higher chances of complications with elastic nailing and can be managed better with bridge plating.(61)

The primary outcome of our study was malunion and in the prospective study, we did not have any malunion in any plane as described previously. This may be because we had totally 8 patients who completed a 6 month follow up and the time for remodelling is not yet complete. In the observational arm, we had 2 malunions (10%) in the plating group and 1 in the nailing group with varus angulation in the coronal plane of more than 15° (5%). This is consistent with the previous report in literature by Ramseir et al.(6) The malunion in the plate group were two: one because the plate deformation occurred in one patient due to a fall and another patient had implant failure. Both the patients had revision surgery with plating and both united within 12 weeks without any further complications. The malunited fracture in the nail group was not revised as it occurred in a child aged 6 years whose angulation was within acceptable limits considering the age and remaining time for remodelling with growth.

We did not have any nerve injuries, infections or compartment syndromes in both, the prospective or the observational arms of the study.

One of the patients who had a fall 2 months post elastic nailing developed a loss of reduction at the fracture site. The child was taken back to theatre and closed reduction/ hip spica application was done for a further 2 months. The fracture united at 13 weeks after the spica application. This child was deemed to have implant failure and also considered in the re-operation group. As the spica was removed at 5 months from the first surgery, the child developed knee stiffness with limitation in ROM of the knee with a range of 10-90° at six months follow up. There were no other implant related complications or reoperations or instances of stiffness in the hip or the knee joint in the randomised control trial group.

In the observational group, the implant related complications were found to be more in the nailing group with nail end irritation in 5 children and 1 malunion due to loss of reduction. Out of the 5 with nail end irritation, 4 children underwent nail exit and 1 child improved over time. The 1(one) child with loss of reduction leading to malunion has been discussed previously. The one implant failure in the plating group underwent implant exit and revision plating and united without any further complication. The data is consistent with literature where there are reports of nail tip irritation . (55, 67, 68).

There were 7 reoperations in the plating group which included 5 elective implant removal as advised based on recent reports in the literature. (42, 62) The remaining two operations were due to malunion which were managed with implant exit and re-plating with no further complications. The 4 reoperations in the nailing group were implant exits due to nail tip irritation managed with implant exits as discussed previously.

The Paediatric outcomes data collection instrument (PODCI) was used to collect functional outcomes in the children which used 6 scales for assessment of functionality of children post injury and intervention. This was administered at 6 months follow up period. Out of the 6 scores, the Upper extremity and physical function core scale, the transfer and basic mobility core scales were not affected as the injury was in the lower limb. There were found to be minimal differences in the sports and physical functioning core scale, the pain/comfort core scale, the Happiness core scale and the Global Functioning core scales. These were not statistically significant. The functional scores were obtained in normative values which were calculated by compiling normal children data to add to a score of 50. A score above 50 was deemed excellent an result. In our study, all PODCI scores were found to be near or above 50 showing good results, more in the plating group. The functional scoring could not be done for children in the observational group.

The duration of stay in the hospital was found to be more for the plating group by 1 day in both the prospective and the observational study groups, which was statistically not significant.

The time taken for union in both the groups was less than 12 weeks in both the groups with a mean of 10 weeks in the nailing and 11.5 weeks in the plating group which was statistically not significant but could be considered clinically relevant as submuscular plating is considered biological without stripping periosteum but there were two open reductions which could have increased the time to union. However, the time to union in our study was lower than that published in previous literature. Ramseier et al had union in plating group at 13.1 weeks and nailing group at 12 weeks(6). Kanlic et al had union at 16 weeks for their submuscular plates.(42) Flynn et al reported union at 10-16 weeks with a mean of 12 weeks. (58) In our observational study, the time to union was 10 and 11.5 weeks in the nailing and plating group respectively, the difference being that more open reductions for fractures with plating were done as compared to the nailing group, thus probably leading to longer time for union in that group.

The time to return to school was found to be lesser in the nailing group by 1.5 weeks which not statistically significant but clinically relevant as time to return to activity and psycho-social factors from the care-givers perspective have been considered important in recent reports.

The median time to return to sports was 12 weeks in both the nailing and plating groups which compare favourably from the previous literature.(6, 58, 69)

The mean duration of surgery was 80 minutes for the nailing group as compared to 100 minutes in the plating group and the data was not statistically significant. The reason for prolonged surgical time could be due to the fact that plating entails many small incisions to guide the plate along the submuscular plane and nailing became more technically easier with experience.

The amount of radiation was quantified with the duration of seconds exposed to a standard portable radiograph machine at a strength of 57-60 kv. The nailing group was found to have mean exposure of 107 seconds as compared to 54 seconds in the plating group (p value – 0.076). This data again was not statistically significant but could be clinically important as increased radiation exposure can be harmful. There have been no reports in literature regarding radiation exposure while plating/nailing.

The amount of blood loss was 100 ml less in the nailing group than the plating group (150ml vs. 250 ml median: p value.846) which was not statistically or clinically significant.

The hospital bills were compared and there was a mean of Rs 34553.29 (standard deviation 8218.13) for plating as compared to 36784.43(standard deviation 6033.65) in the nailing group in the prospective arm. It was roughly 3000 rupees difference in both the groups as compared to the observational study which could be accounted for by increase in the hospital charges and inflation.

CONCLUSIONS

This is the first randomised study to prospectively compare two surgical interventions namely ESIN and LCP in the age group 5-16 years. There was no difference in malunion rates between the plating and ESIN group. However, there were significant trends related to blood loss in the plating group as compared to nailing with lesser blood loss in the nailing group. Functionally, there was an earlier trend to return to school in the nailing group, along with a trend to faster union rates which can have an important relevance from the care givers perspective.

The exposure to radiation was lesser in the plating group and better functional scores were obtained in the plating group.

Looking at the trends, sub muscular plating appears to be a viable alternative to the current accepted standard of care, which is elastic stable intramedullary nailing (ESIN) in the 5-16 year age group.

However as the numbers were small in the prospective arm, larger number of patients need to be analysed for a longer duration of time before drawing definite conclusions.

LIMITATIONS

Although a thorough literature review and screening the study through a watchful institutional review board was done, the limitations and the mistakes were minimised but there were still a few factors which minimised the effect of study. These are

a. Duration of study from September2013-September 2014 was not enough to gather enough number of patients to draw definitive conclusions.
b. Due to rigid exclusion criteria, quite a few patients could not be included in the study.
c. The primary outcome assessment was restricted due to a minimum period of 6 months follow-up.

SCOPE OF STUDY

The scope that this study has opened is vast. This study has introduced sub-muscular plating as an alternative to the elastic stable intramedullary nailing rather than as adjunct to it. Though the numbers are small, the trends are promising and this randomised study has been planned to continue and recruit more patients, so as to facilitate a more robust analysis and helping in drawing definitive conclusions.

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ANNEXURE

Nailing technique

Place the child in a supine position on a radiolucent operating table. The fracture table can be used for larger children. Position the image intensifier so that AP and lateral x-rays can be recorded over the full length of the femur.

Measure the isthmus of the medullary canal on the x-ray image. The diameter of the individual nail should be 40% of the narrowest diameter of the medullary canal. Choose nails with identical diameter, so that the opposing bending forces are equal, avoiding malalignment with varus or valgus malpositioning.

Pre-bend nail for a good contact of the nail with the inner side of the cortex is essential, especially for long oblique, spiral or complex fractures, where a danger of shortening exists. It is recommended to pre-bend the nail over the length of the bone three times the diameter of the medullary canal. The vertex of the arch should be located at the level of the fracture zone. Both nails should be pre-contoured in the same way.

Make one incision in each case on the lateral and medial aspects of the distal femur, starting at the planned entry point, and extend distally for 2 – 4 cm depending on the child's size.

The insertion points on the femur should be 1 to 2 cm proximal to the distal physis. In children, this is about one fingerbreadth proximal to the upper pole of the patella.

Precisely matched openings of the medullary canal on both sides are essential for optimal symmetrical bracing.

Load the first nail in the inserter. Align the laser marking on the straight nail end with one of the guide markings on the inserter. Tighten the nail in the inserter in the desired position using the pin wrench or the spanner wrench. Insert the nail into the medullary canal with the nail tip at right angles to the bone shaft. Rotate the nail through 180° with the inserter and align the nail tip with the axis of the medullary canal. Advance the nail manually up to the fracture site, using oscillating movements or with gentle blows to the impaction surface of the inserter using the slotted part of the combined hammer. Drive the first nail to the level of the fracture.

At the insertion point on the opposite side, open the medullary canal in the same manner. Pre-bend a nail of identical diameter in the same way, insert into the metaphysis and advance up to the fracture zone.

The proximal fragment can be manipulated and precise reduction can be achieved by means of protruding nails using the so called "joystick" technique. When the cavities are aligned correctly, advance the nails alternately with gentle hammer blows or oscillating movements far enough across the fracture zone to ensure that the main fragments are held firmly. Then advance the nails as far as the metaphysis. The tips of the nails in the proximal fragment must be correctly aligned in the frontal plane.

At this point check the stability and rotation. Once the nails are fixed in the metaphysis it is no longer possible to adjust the rotation if the nail tips in the proximal fragment are correctly located, then the nails can be shortened to the required length with the cutter for TEN, which allows the nails to be cut very close to the bone cortex. The end cap is inserted over the correctly cut end of the nail and threaded into the metaphysis obliquely.

Source - http://www.synthes.com/MediaBin/International%20DATA/036.000.207.pdf

Plating technique

The patient is positioned supine on either a fracture table or a radiolucent table. Plate length is established by laying the plate over the thigh while using fluoroscopy to visualize the femoral fracture. A long plate should be used to permit greater distance between the screws; an average plate has 12 to 16 holes. A plate bender is used to contour the proximal and distal portions of the plate to fit the proximal and distal femoral metaphyseal flares. The central portion of the plate should remain straight to match normal femoral anatomy. It is not necessary to bend the plate to match the anterior bow of the femur.

A small lateral incision (2 to 3 cm in length) is made over the distal femur. The iliotibial band is split longitudinally, and the vastus lateralis is elevated anteriorly off the distal femur. A Cobb elevator is passed extraperiosteally between the lateral femur and the vastus lateralis. The plate is then inserted and advanced proximally while traction is used to maintain fracture length. The plate should be advanced slowly such that contact between the plate and the femur can be felt. This allows redirection of the plate if it passes anterior or posterior to the femur. Fluoroscopy can be used to assist with plate advancement. For subtrochanteric and proximal third femoral fractures, a proximal lateral incision can be made, and the plate is inserted in a proximal-to-distal direction.

Next, AP and lateral fluoroscopic images are used to confirm final plate position and to ensure that fracture length has been reestablished. Kirschner wires are placed in the proximal- and distal-most screw holes to secure the plate to the femur. This stabilizes the length of the fracture. If the fracture is angulated in recurvatum, a bolster can be placed under the thigh, or an additional Kirschner wire can be inserted through the middle of the plate to correct this issue.

The first screw is inserted through the distal incision under direct visualization, and the remaining screws are inserted percutaneously. The second screw can be used to reduce the femur to the plate and should be placed just proximal or distal to the fracture, where the femur is farthest from the plate. The perfect circle technique can be used to assist with percutaneous screw placement. A stab incision is made through the soft tissues of the lateral thigh. Fluoroscopy is used to guide placement of a 3.2-mm drill bit into the desired hole in the plate. The drill is positioned perpendicular to the plate and is advanced through both cortices. The depth gauge is placed over the anterior thigh, and fluoroscopy is used to determine screw length. Self-tapping screws are used to avoid percutaneous insertion of a tap through the soft tissues. An absorbable suture is tied around the head of the screw to maintain control as the screw is inserted. The remaining screws are placed in a similar fashion. Placement of three screws proximal and distal to the fracture typically provides adequate stability. The screws should be placed far apart to achieve maximum stability. No lag screws are necessary. Final radiographs are obtained to confirm acceptable reduction and alignment.

No postoperative immobilization is required. Patients can begin immediate hip and knee range-of-motion exercises. Toe-touch weight bearing with crutches is allowed until radiographs demonstrate callus formation, generally at 6 to 8 weeks postoperatively. Weight bearing is then advanced as tolerated, and patients are allowed to gradually return to activity. The plate can be removed at approximately 6 months postoperatively.

Source - Li Y, Hedequist DJ. Submuscular plating of pediatric femur fracture. J Am Acad Orthop Surg. 2012 Sep; 20(9):596–603

CLINICAL RESEARCH PROFORMA

A randomized trial comparing intramedullary titanium elastic nailing with locked compression plating

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Randomization number:
Name of the child
Hospital number
Name of the consenting parent/guardian
Address
Phone number
Email address
Height (cm) Weight (kg) BMI (kg/m^2)
Mechanism of injury
Date of injury
Time take to seek treatment (hrs)
Side of injury

Operative procedure chosen by randomization
Surgeon:
Fracture type: _________________________
Duration for surgery: _ _ _ minutes
Intraoperative blood loss: _ _ _ mL
Post Operative X-Ray:
Cost of treatment:

Paediatric outcomes data collection instrument (PODCI)

Visit Number: 6months / 12 months / 24 months

Adolescent Health Assessment
Some kind of problems can make it hard to do many activities, such as eating, bathing, school work, and playing with friends. We would like to find out how you are doing. (Choose one response per line.)

During the last week was it easy or hard for you to: 1- Easy 2- A little hard 3 - Very hard 4 - Can't do at all
1 .Lift heavy books
2. Pour a half gallon of milk?
3. Open a jar that has been opened before?
4. Use a fork and spoon?
5. Comb your hair?
6. Button buttons?
7. Put on your coat?
8. Write with a pencil?

9. **On average, over the last 6 months how often did you miss school (camp, etc.) because of your health?**
Rarely / Once a month / Two or three times a month / Once a week / More than once a week / Do not attend school.

During the last week how happy have you been with: 1 - Very happy 2 - Somewhat happy 3 - Not sure 4 – Somewhat unhappy 5 - Very unhappy
10. How you look?
11. Your body?
12. What clothes or
Shoes you can wear?
13. Your ability to do the
Same things your friends do?
14. Your health in general?

During the last week how much of the time: 1-Most of the time 2 - Some of the time 3 - A little of the time 4 - None of the time
15. Did you feel sick and tired?
16. Were you full of pep and energy?
17. Did pain or discomfort interfere with your activities?

During the last week has it been easy or hard for you to: 1 – Easy 2 - A little hard 3 - Very hard 4 - Can't do at all
18. Run short distances?
19. Bicycle or tricycle?
20. Climb three flights of stairs?

21. Climb one flight of stairs?
22. Walk more than a mile?
23. Walk three blocks?
24. Walk one block?
25. Get on and off a bus?

26. **How often do you need help from another person for walking and climbing?** 1 – Never 2 – Sometimes 3 - About half the time 4 – Often 5- All the time

27. **How often do you use assistive devices (such as braces, crutches, or wheelchair) for walking and climbing?**
1 – Never 2 – Sometimes 3 - About half the time 4 – Often 5 - All the time

During the last week, has it been easy or hard for you to: 1 – Easy 2 - A little hard 3 - Very hard 4 - Can't do at all
28. Stand while washing your hands
And face at a sink?
29. Sit in a regular chair without
Holding on?
30. Get on and off a toilet or chair?
31. Get in and out of bed?
32. Turn door knobs?
33. Bend over from a standing position and pick up something off the floor?

34. **How often do you need help from another person for sitting and standing?**
1 – Never 2 – Sometimes 3 - About half the time 4 – Often 5 - All the time

35. **How often do you use assistive devices (such as braces, crutches, or wheelchair) for sitting and standing**?
1 – Never 2 – Sometimes 3 - About half the time 4 – Often 5 - All the time

36. Can **you participate in recreational outdoor activities with other kids the same age?** (For example: bicycling, skating, hiking, and jogging)
1 - Yes, easily 2 - Yes, but a little hard 3 - Yes, but very hard 4 - No

If you answered "no" to Question 36 above, was your activity limited by: (Choose all that apply.)
37. Pain?
38. General health?
39. Doctor or parent instructions?
40. Fear the other kids won't like you?
41. Dislike of recreational outdoor activities?
42. Activity not in season?

43. **Can you participate in pickup games or sports with other kids the same age?** (For example: tag, dodge ball, basketball, softball, soccer, catch, jump rope, touch football, hop scotch)

1 - Yes, easily 2 - Yes, but a little hard 3 - Yes, but very hard 4 - No

If you answered "no" to Question 43 above, was your activity limited by: (Choose all that apply.)

44. Pain?
45. General health?
46. Doctor or parent instructions?
47. Fear the other kids won't like you?
48. Dislike of pickup games or sports?
49. Activity not in season?

50. **Can you participate in competitive level sports with other kids the same age?** (For example: hockey, basketball, soccer, football, baseball, swimming, running [track or cross country], gymnastics, or dance)

1-Yes, easily 2 - Yes, but a little hard 3 - Yes, but very hard 4 - No

If you answered "no" to Question 50 above, was your child's activity limited by: (Choose all that apply.)

51. Pain?
52. General health?
53. Doctor or parent instructions?
54. Fear the other kids won't like you?
55. Dislike of competitive level sports?
56. Activity not in season?

57 **How often in the last week did you get together and do things with friends?**

1 – Often 2 – Sometimes 3 - Never or rarely

If you answered "sometimes" or "never or rarely" to Question 57 above, was your activity limited by: (Choose all that apply.)

58. Pain?
59. General health?
60. Doctor or parent instructions?
61. Fear the other kids won't like you?
62. Friends not around?

63. **How often in the last week did you participate in gym/recess?** (Choose one response.)

1 – Often 2 – Sometimes 3 - Never or rarely 4 - No gym or recess

If you answered "sometimes" or "never or rarely" to Question 63 above, was your activity limited by: (Choose all that apply.)

64. Pain?
65. General health?
66. Doctor or parent instructions?
67. Fear the other kids won't like you?
68. Dislike of gym/recess?

69. School not in session?
70. I don't attend school?

71. **is it easy or hard for you to make friends with kids your own age?**
1 - Usually easy 2 - Sometimes easy 3 - Sometimes hard 4- usually hard

72**. How much pain have you had during the last week?**
1 – None 2 - Very mild 3 – Mild 4 – Moderate 5 – Severe 6 - Very severe

73. **During the last week how much did pain interfere with your normal activities**
(including at home, outside of the Home, and at school)?
1 - Not at all 2 - A little bit 3 – Moderately 4 – Quite a bit 5 – Extremely

What expectations do you have for your treatment?
As a result of my treatment, I expect: 1 - Definitely yes 2 - Probably yes 3 - Not sure 4 - Probably not 5 - Definitely not
74. To have pain relief.
75. To look better.
76. To feel better about myself.
77. To sleep more comfortably.
78.To be able to do activities at home.
79. To be able to do more at school.
80. To be able to do more play or recreational activities
(biking, walking, doing things with friends).
81.To be able to do more sports.
82.To be free from pain or disability as an adult.
83. If you had to spend the rest of your life with your bone and muscle condition as it is right now how would you feel
about it? 1 - Very satisfied 2 - Somewhat satisfied 3 – Neutral 4 – Somewhat dissatisfied 5 - Very dissatisfied

Malunion –
a) >15° of angulation in the coronal plane (varus or valgus): Yes / No

b) >20° of angulation in the sagittal plane (anterior or posterior): Yes / No

c) Clinically obvious malrotation (an asymmetric foot progression angle with corresponding asymmetry of internal or external rotation of the hip): Yes / No

d) Limb-length discrepancy of >2.0 cm: Yes / No

Non-union: Yes / No

Infection: Yes / No

Reoperation: Yes / No

Time for return to usual activity in days:

1. **Ambulation : _____ days,**
2. **School: _____ days,**

3. **Play: _____ days,**

Nerve injuries: Yes / No**,**

Compartment syndrome: Yes / No**,**

Decrease Range of Movement (ROM) in proximal and distal joint as compared to the opposite side:

1. Hip: Yes / No
2. Knee: Yes / No

Implant related complications: _________________________________

Prospective data sheet

sno	name	hospnum	age	area	moi	doi	tstx	side
1	VENKATESAN	675503F	10	1	1	########	3	1
2	SAKTHIVEL	675896F	14	2	2	########	5	1
3	SAI KRISHNAMOORTHY	688902F	7	4	1	########	1	2
4	BHARATH	751249F	5	1	1	########	1	2
5	BHARATH	753504F	5	2	1	########	22	1
6	ALIM BASHA	754744F	8	2	1	########	8	2
7	DEESHITHA	754903F	10	1	1	########	1	1
8	GOKULAKRISHNAN	899012D	7	1	1	########	6	1
9	GOUTHAM	907156F	14	1	1	########	1	1
10	SWETHA	909735F	6	2	1	########	1	1
11	MOHAN KUMAR	212558F	7	1	1	########	12	1
12	SRIMATHI	912558F	9	1	1	########	5	1
13	LOGESWARAN	914913F	14	1	1	########	1	2
14	JEYANTHI	915656F	8	1	1	########	1	1

fxty	mod	sur	rad	amtrad	red	dusx	blloss	dusy
3	1	2	1	54	2	65	30	6
1	1	2	1	43	2	90	100	5
1	2	6	0		2	90	50	8
2	2	2	1	119	2	110	100	2
1	1	6	1	120	2	120	75	6
2	2	1	1	87	2	75	50	3
2	2	4	1	173	2	75	100	4
1	1	7	1	68	2	105	75	5
2	2	1	1	107	2	80	100	5
2	1	7	1	32	2	70	50	3
1	1	6	0		1	100	250	4
	2	8	0		2	108	150	4
2	1	6	0		1	120	175	11
1	2	7	1	69	2	80	50	4

cost	fudur	mal	cor	sag	rot	lld	inf	resx	retactiv
36090	12	0	0	0	0	0	0	0	
33416	11	0	0	0	0	0	0	0	1
45482	11	1	0	0	0	0	0	0	
29439	8	0	0	0	0	0	0	0	
30405	8	0	0	0	0	0	0	0	
40000	7	0	0	0	0	0	0	0	
41314	7	0	0	0	0	0	0	1	2
31076	6	0	0	0	0	0	0	0	
33180	4						0	0	
23886	3						0	0	1
36486	3						0	0	1
37904	2						0	0	
50514	2						0	0	
30172	1						0	0	

retsport	neuro	compart	implant	stiff	hip	knee	timeunion	podci
12	0	0	0	0			12	1
16	0	0	0	0			12	1
12	0	0	0	0			10	1
12	0	0	0	0			12	1
11	0	0	0	0			11	1
10	0	0	0	0			10	1
27	0	0	1	1	0	1	21	1
12	0	0	0	0			9	1
12	0	0	0	0			9	0
12	0	0	0	0				0
	0	0	0	0				0
	0	0	0	0				0
	0	0	0	0				0
	0	0	0	0				0

normative1	normative2	normative3	normative4	normative5	normative6	injsxint
57	53	29	55	40	49	60
57	53	53	55	57	57	28
57	53	53	55	57	57	13
57	53	57	55	57	58	5
57	53	57	55	57	58	65
57	55	57	53	57	58	21
57	48	8	28	48	23	14
57	53	55	55	57	57	14
						12
						10
						28
						24
						18
						14

Data – observational study

sno	name	hospnum	age	area	moi	side	fxty	mod
1	sattik mahapatra	062681f	11	4	3	1	1	1
2	venkatesan	299471f	15	3	1	1	1	1
3	manigandan	364867f	15	2	1	1	2	1
4	hemanth kumar	328177f	11	1	1	2	1	1
5	sunil kumar	389255f	15	2	3	1	1	1
6	padaiyappa	415442f	16	1	2	2	2	1
7	deepika	422320f	10	1	1	1	1	1
8	salma	422627f	7	2	3	1	1	1
9	vignesh	845218d	13	1	3	1	1	1
10	saivamsi kumar reddy	611489f	10	3	1	1	1	1
11	mukesh	908987d	13	3	1	2	2	1
12	ramya	207465f	8	1	1	1	2	1
13	sankari	136053f	9	2	1	2	2	1
14	sankari	136053f	9	2	1	1	1	2
15	kumaravel	062248f	15	1	1	1	4	1
16	vignesh	222312f	15	2	1	2	3	1
17	idayath	384608f	5	3	2	1	1	2
18	kavaiya	422311f	7	1	1	2	2	2
19	pasupathy	495402f	11	1	3	1	1	2
20	baskar	611673f	10	1	1	1	3	2
21	ibrahim	671570f	15	1	2	2	2	2
22	Udaya kumar	152067f	13	3	2	1	1	2
23	vijay	612611c	10	2	1	1	1	2
24	danush	211621f	8	1	1	1	1	2
25	ragul	889613b	12	1	1	1	1	2
26	suriya	227869f	13	1	3	1	1	2
27	suriya	227869f	13	1	3	2	1	2
28	vasanth kumar	136121f	12	1	1	1	1	2
29	sridarshini	709685c	11	2	1	1	1	2
30	mohan raj	547580c	7	1	1	1	1	2
31	venkatesh	675503f	10	1	1	1	3	1
32	sakthivel	679856f	14	2	2	1	1	1
33	sai krishna	688902f	7	4	1	2	1	2
34	bharath	751249f	5	1	1	2	2	2
35	harish kumar	753504f	5	2	1	1	1	1
36	alim basha	754744f	8	2	1	2	2	2
37	deeshitha	754903f	10	1	1	1	2	2
38	gokulakrishnan	899012d	7	1	1	1	1	1
39	goutham	907156f	14	1	1	1	2	2
40	swetha	909735f	6	2	1	1	2	1

red	dusx	blloss	dusy	cost	fudur	mal	cor	sag	rot
1	90	100	6	18234	18	0	0	0	0
2	80	150	6	46555	13	1	1	0	0
2	70	50	6	26602	4	0	0	0	0
1	90	100	5	21898	12	0	0	0	0
1	110	50	6	34329	4	0	0	0	0
1	120	150	7	35661	5	0	0	0	0
2	150	175	4	45321	14	0	0	0	0
2			5	34878	14	0	0	0	0
1	180	400	7	39323	9	0	0	0	0
2	70	100	8	25336	14	0	0	0	0
1			5	26493	14	1	1	0	0
2	120	50	5	21854	15	0	0	0	0
1	120	225	7	33174	5	0	0	0	0
2	120	75	7	33174	5	0	0	0	0
2	180	150	6	39626	32	0	0	0	0
1	80	150	12	50931	24	0	0	0	0
2	90	50	4	35515	13	0	0	0	0
2	120	70	3	40069	15	0	0	0	0
1	100	60	3	37472	4	0	0	0	0
1	120	250	11	59676	12	0	0	0	0
1	90	75	5	35057	6	0	0	0	0
2	75	50	6	27450	5	0	0	0	0
2	90	50	6	28901	5	0	0	0	0
2	75	30	4	23211	12	0	0	0	0
2	70	50	4	27240	4	0	0	0	0
2	150	50	6	15677	6	0	0	0	0
1	150	50	6	10000	6	0	0	0	0
1	130	70	6	29233	6	0	0	0	0
2	110	50	6	36867	26	0	0	0	0
2	100	70	5	22010	11	0	0	0	0
2	65	30	6	36090	12	0	0	0	0
2	90	100	5	33416	11	0	0	0	0
2	90	50	8	45482	11	0	0	0	0
2	110	1001	2	29439	8	0	0	0	0
2	120	75	6	30405	8	0	0	0	0
2	75	50	3	40000	7	0	0	0	0
2	75	100	4	41314	7	0	0	0	0
2	105	75	5	31076	6	0	0	0	0
2	80	100	5	33180	4	0	0	0	0
2	70	50	3	23886	3	0	0	0	0

lld	inf	resx	neuro	compart	implant	stiff	hip	knee	timeunion
0	0	0	0	0	0	0			14
0	0	1	0	0	0	0			16
0	0	0	0	0	0	0			15
0	0	1	0	0	0	0			12
0	0	0	0	0	0	0			7
0	0	0	0	0	0	0			12
0	0	0	0	0	0	0			16
0	0	0	0	0	0	0			7
0	0	0	0	0	0	0			11
0	0	1	0	0	0	0			10
0	0	1	0	0	0	0			14
0	0	1	0	0	0	0			11
0	0	0	0	0	0	0			9
0	0	0	0	0	0	0			9
0	0	1	0	0	1	0			20
0	0	1	0	0	0	0			13
0	0	0	0	0	0	0			7
0	0	1	0	0	1	0			10
0	0	0	0	0	1	0			10
0	0	0	0	0	0	0			10
0	0	0	0	0	0	0			15
0	0	0	0	0	0	0			12
0	0	0	0	0	0	0			10
0	0	0	0	0	1	0			12
0	0	0	0	0	0	0			16
0	0	0	0	0	0	0			10
0	0	0	0	0	0	0			10
0	0	0	0	0	0	0			14
0	0	1	0	0	1	0			14
0	0	1	0	0	1	0			12
0	0	0	0	0	0	0			12
0	0	0	0	0	0	0			12
0	0	0	0	0	0	0			10
0	0	0	0	0	0	0			12
0	0	0	0	0	0	0			11
0	0	0	0	0	0	0			10
0	0	1	0	0	1	1	0	1	21
0	0	0	0	0	0	0			9
0	0	0	0	0	0	0			9
0	0	0	0	0	0	0			10